

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA \geq 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Overall		Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	5/308 (1.6%)	3/308 (1.0%)
		OR (95% CI) p value	1.6703 (0.3953, 7.0585) 0.485	
		RD (95% CI) p value	0.6491 (-1.1552, 2.4534) 0.481	
		RR (95% CI) p value	1.6614 (0.4007, 6.8877) 0.484	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA \geq 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

18OCT2019 01:58

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA ≥ 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Age (years)	<35	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	0/80	1/80 (1.3%)
		OR (95% CI)	0.0000 (0.0000, I)	
		p value	1.000	
		RD (95% CI)	-1.2319 (-3.6699, 1.2062)	
		p value	0.322	
		RR (95% CI)	NC	
		p value	NC	
		P value for interaction	0.331	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA ≥ 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA ≥ 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Age (years)	35 - <50	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	4/162 (2.5%)	1/132 (0.8%)
		OR (95% CI) p value	3.1526 (0.3428, 28.9904) 0.310	
		RD (95% CI) p value	1.6587 (-1.2433, 4.5608) 0.263	
		RR (95% CI) p value P value for interaction	3.0740 (0.3455, 27.3467) 0.314 0.331	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA ≥ 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA ≥ 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Age (years)	≥ 50	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	1/66 (1.5%)	1/96 (1.0%)
		OR (95% CI)	1.4569 (0.0873, 24.3050)	
		p value	0.793	
		RD (95% CI)	0.4680 (-3.3003, 4.2363)	
		p value	0.808	
		RR (95% CI)	NC	
		p value	NC	
		P value for interaction	0.331	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA ≥ 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA \geq 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Sex at Birth	Female	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	2/99 (2.0%)	0/104
		OR (95% CI)	3.027E11 (3.027E11, 3.027E11)	
		p value	NC	
		RD (95% CI)	2.0391 (-0.7452, 4.8234)	
		p value	0.151	
		RR (95% CI)	NC	
		p value	NC	
		P value for interaction	0.124	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA \geq 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA ≥ 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Sex at Birth	Male	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	3/209 (1.4%)	3/204 (1.5%)
		OR (95% CI) p value	0.9768 (0.1943, 4.9098) 0.977	
		RD (95% CI) p value	-0.0336 (-2.3547, 2.2876) 0.977	
		RR (95% CI) p value P value for interaction	0.9827 (0.2011, 4.8016) 0.983 0.124	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA ≥ 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA \geq 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Race	White	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	3/214 (1.4%)	2/207 (1.0%)
		OR (95% CI) p value	1.4628 (0.2414, 8.8652) 0.679	
		RD (95% CI) p value	0.3860 (-1.6806, 2.4526) 0.714	
		RR (95% CI) p value P value for interaction	1.4594 (0.2464, 8.6427) 0.677 0.786	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA \geq 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA \geq 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Race	Non-White	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	2/94 (2.1%)	1/101 (1.0%)
		OR (95% CI) p value	2.2032 (0.1949, 24.9019) 0.523	
		RD (95% CI) p value	1.1181 (-2.4315, 4.6678) 0.537	
		RR (95% CI) p value P value for interaction	2.1606 (0.1997, 23.3767) 0.526 0.786	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA \geq 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

18OCT2019 01:58

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA \geq 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Region	North America	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	0/93	2/107 (1.9%)
		OR (95% CI) p value	0.0000 (0.0000, I) 1.000	
		RD (95% CI) p value	-1.9382 (-4.5563, 0.6798) 0.147	
		RR (95% CI) p value P value for interaction	NC NC 0.081	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA \geq 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA \geq 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Region	Europe	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	4/145 (2.8%)	1/146 (0.7%)
		OR (95% CI) p value	4.0956 (0.4491, 37.3492) 0.211	
		RD (95% CI) p value	2.0866 (-0.9057, 5.0789) 0.172	
		RR (95% CI) p value P value for interaction	3.9779 (0.4507, 35.1112) 0.214 0.081	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA \geq 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA ≥ 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Region	Rest of World	Number of Subjects with HIV-1 RNA ≥ 50 c/mL/Total Assessed	1/70 (1.4%)	0/55
		OR (95% CI)	3.967E11 (3.967E11, 3.967E11)	
		p value	NC	
		RD (95% CI)	1.3434 (-1.3922, 4.0789)	
		p value	0.336	
		RR (95% CI)	NC	
		p value	NC	
		P value for interaction	0.081	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA ≥ 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA \geq 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Baseline third agent class	PI	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	1/51 (2.0%)	0/54
		OR (95% CI) p value	2.782E11 (2.782E11, 2.782E11) NC	
		RD (95% CI) p value	2.0202 (-1.8415, 5.8819) 0.305	
		RR (95% CI) p value P value for interaction	NC NC 0.056	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA \geq 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA \geq 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Baseline third agent class	INI	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	0/102	2/99 (2.0%)
		OR (95% CI) p value	0.0000 (0.0000, I) 1.000	
		RD (95% CI) p value	-2.0399 (-4.8247, 0.7450) 0.151	
		RR (95% CI) p value P value for interaction	NC NC 0.056	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA \geq 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA \geq 50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Baseline third agent class	NNRTI	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	4/155 (2.6%)	1/155 (0.6%)
		OR (95% CI) p value	4.0701 (0.4491, 36.8878) 0.212	
		RD (95% CI) p value	1.9279 (-0.8654, 4.7213) 0.176	
		RR (95% CI) p value P value for interaction	3.9737 (0.4498, 35.1048) 0.215 0.056	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). Zero counts for subjects with HIV-1 RNA \geq 50 c/ml in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Overall		Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	285/308 (93%)	294/308 (95%)
		OR (95% CI) p value	0.5875 (0.2963, 1.1651) 0.128	
		RD (95% CI) p value	-2.9815 (-6.7071, 0.7440) 0.117	
		RR (95% CI) p value	0.9694 (0.9314, 1.0091) 0.129	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

18OCT2019 01:59

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Age (years)	<35	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	73/80 (91%)	77/80 (96%)
		OR (95% CI) p value	0.4246 (0.1042, 1.7301) 0.232	
		RD (95% CI) p value	-4.9176 (-12.4131, 2.5778) 0.198	
		RR (95% CI) p value P value for interaction	0.9623 (0.8548, 1.0833) 0.525 0.738	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Age (years)	35 - <50	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	149/162 (92%)	125/132 (95%)
		OR (95% CI) p value	0.6317 (0.2422, 1.6476) 0.348	
		RD (95% CI) p value	-2.9738 (-8.5921, 2.6446) 0.300	
		RR (95% CI) p value P value for interaction	0.9591 (0.8949, 1.0278) 0.237 0.738	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Age (years)	>=50	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	63/66 (95%)	92/96 (96%)
		OR (95% CI)	0.8825 (0.1893, 4.1135)	
		p value	0.874	
		RD (95% CI)	-0.2880 (-6.8915, 6.3155)	
		p value	0.932	
		RR (95% CI)	1.0123 (0.9270, 1.1056)	
		p value	0.785	
		P value for interaction	0.738	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Sex at Birth	Female	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	92/99 (93%)	98/104 (94%)
		OR (95% CI) p value	0.7843 (0.2516, 2.4448) 0.675	
		RD (95% CI) p value	-1.4305 (-8.1252, 5.2641) 0.675	
		RR (95% CI) p value P value for interaction	0.9843 (0.9215, 1.0514) 0.638 0.574	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Sex at Birth	Male	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	193/209 (92%)	196/204 (96%)
		OR (95% CI) p value	0.4889 (0.2039, 1.1726) 0.109	
		RD (95% CI) p value	-3.7433 (-8.2125, 0.7260) 0.101	
		RR (95% CI) p value P value for interaction	0.9633 (0.9066, 1.0236) 0.228 0.574	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Race	White	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	200/214 (93%)	199/207 (96%)
		OR (95% CI)	0.5745 (0.2352, 1.4035)	
		p value	0.224	
		RD (95% CI)	-2.5282 (-6.7277, 1.6712)	
		p value	0.238	
		RR (95% CI)	0.9599 (0.9086, 1.0141)	
		p value	0.144	
		P value for interaction	0.936	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

18OCT2019 01:59

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Race	Non-White	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	85/94 (90%)	95/101 (94%)
		OR (95% CI)	0.5661 (0.1909, 1.6794)	
		p value	0.305	
		RD (95% CI)	-4.2983 (-11.8186, 3.2221)	
		p value	0.263	
		RR (95% CI)	0.9273 (0.8377, 1.0264)	
		p value	0.145	
		P value for interaction	0.936	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Region	North America	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	88/93 (95%)	99/107 (93%)
		OR (95% CI) p value	1.4774 (0.4518, 4.8316) 0.519	
		RD (95% CI) p value	2.4920 (-4.6002, 9.5842) 0.491	
		RR (95% CI) p value P value for interaction	1.0200 (0.9572, 1.0869) 0.541 NC	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Region	Europe	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	135/145 (93%)	140/146 (96%)
		OR (95% CI) p value	0.5892 (0.2072, 1.6754) 0.321	
		RD (95% CI) p value	-2.7811 (-8.1136, 2.5513) 0.307	
		RR (95% CI) p value P value for interaction	0.9674 (0.8950, 1.0457) 0.404 NC	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Region	Rest of World	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	62/70 (89%)	55/55 (100%)
		OR (95% CI) p value	0.0000 (0.0000, 0.0000) NC	
		RD (95% CI) p value	-10.4152 (-17.7034, -3.1271) 0.005	
		RR (95% CI) p value P value for interaction	NC NC NC	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Baseline third agent class	PI	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	47/51 (92%)	51/54 (94%)
		OR (95% CI) p value	0.6480 (0.1334, 3.1493) 0.591	
		RD (95% CI) p value	-2.5814 (-11.9591, 6.7964) 0.590	
		RR (95% CI) p value P value for interaction	0.9650 (0.7853, 1.1858) 0.735 0.881	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Baseline third agent class	INI	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	96/102 (94%)	95/99 (96%)
		OR (95% CI) p value	0.6724 (0.1838, 2.4596) 0.549	
		RD (95% CI) p value	-1.8508 (-7.8394, 4.1377) 0.545	
		RR (95% CI) p value P value for interaction	0.9803 (0.9203, 1.0442) 0.537 0.881	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA <50 copies/mL at Week 48
 - Overall and by Subgroup - Snapshot Analysis - ATLAS

Subgroup	Category	Measure	Q4W IM (N=308)	Current ART (N=308)
Baseline third agent class	NNRTI	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	142/155 (92%)	148/155 (95%)
		OR (95% CI) p value	0.5171 (0.2001, 1.3358) 0.173	
		RD (95% CI) p value	-3.8496 (-9.2916, 1.5925) 0.166	
		RR (95% CI) p value P value for interaction	0.9636 (0.9089, 1.0215) 0.213 0.881	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For RD, statistical measures are obtained from Cochran-Mantel Haenszel stratified analysis adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'), adjusting for sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment, sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI).
 NC = Not Calculable.

PPD

Table 2.03
 Summary of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³) at Week 48
 - Overall and by Subgroup - ATLAS

Subgroup: Overall

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Overall	Q4W IM	308	Baseline	308	678.5	257.11	653.5	497.0	816.0	185	1903
			Week 48	263	685.3	262.97	637.0	503.0	830.0	167	1939
			Change	263	9.9	187.24	4.0	-89.0	114.0	-536	801
	Current ART	308	Baseline	308	692.8	288.74	652.5	488.0	843.5	150	2543
			Week 48	290	716.7	292.85	684.0	488.0	897.0	214	2426
			Change	290	19.4	168.80	13.5	-70.0	107.0	-1043	521

Note: Summaries at Baseline and Week 48 are actual values, Change represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

11OCT2019 03:44

Table 2.03
 Summary of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³) at Week 48
 - Overall and by Subgroup - ATLAS

Subgroup: Age (years) (< 35 vs. >= 35 - < 50 vs. >= 50)

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
<35	Q4W IM	80	Baseline	80	734.9	266.96	714.5	507.5	962.0	229	1370
			Week 48	70	758.7	289.51	728.5	544.0	932.0	167	1939
			Change	70	10.9	209.36	1.5	-96.0	99.0	-474	801
	Current ART	80	Baseline	80	726.2	259.16	724.0	559.0	881.0	209	1394
			Week 48	76	735.6	240.80	717.0	590.5	880.5	224	1343
			Change	76	1.7	184.29	36.5	-116.0	102.0	-603	460
35 - <50	Q4W IM	162	Baseline	162	662.2	229.00	655.5	490.0	797.0	215	1616
			Week 48	135	690.9	233.69	634.0	520.0	829.0	234	1476
			Change	135	23.6	175.29	20.0	-74.0	125.0	-398	488
	Current ART	132	Baseline	132	688.7	311.16	643.5	483.5	829.5	248	2543
			Week 48	123	721.6	310.11	687.0	493.0	898.0	214	2426
			Change	123	29.9	181.80	19.0	-54.0	118.0	-1043	439
>=50	Q4W IM	66	Baseline	66	650.2	300.54	614.0	498.0	742.0	185	1903
			Week 48	58	583.6	266.11	532.0	401.0	690.0	198	1644
			Change	58	-23.1	185.23	-36.0	-125.0	58.0	-536	456
	Current ART	96	Baseline	96	670.6	280.36	621.0	447.0	834.0	150	1370
			Week 48	91	694.2	309.62	615.0	441.0	904.0	217	1602
			Change	91	20.1	134.07	8.0	-75.0	84.0	-270	521

Note: Summaries at Baseline and Week 48 are actual values, Change represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

11OCT2019 03:44

Table 2.03
 Summary of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³) at Week 48
 - Overall and by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Female	Q4W IM	99	Baseline	99	653.1	275.25	612.0	465.0	783.0	293	1903
			Week 48	86	678.1	261.98	624.0	505.0	788.0	308	1939
			Change	86	41.4	196.05	36.5	-80.0	152.0	-398	801
	Current ART	104	Baseline	104	695.9	272.53	668.5	501.5	846.0	209	1797
			Week 48	97	718.2	292.66	657.0	483.0	920.0	224	1629
			Change	97	20.1	169.20	6.0	-88.0	94.0	-366	521
Male	Q4W IM	209	Baseline	209	690.6	247.83	674.0	515.0	826.0	185	1616
			Week 48	177	688.8	264.13	658.0	503.0	836.0	167	1644
			Change	177	-5.4	181.41	-10.0	-96.0	85.0	-536	488
	Current ART	204	Baseline	204	691.2	297.31	644.5	472.5	842.0	150	2543
			Week 48	193	716.0	293.71	690.0	493.0	882.0	214	2426
			Change	193	19.1	169.04	19.0	-54.0	108.0	-1043	439

Note: Summaries at Baseline and Week 48 are actual values, Change represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

11OCT2019 03:44

Table 2.03
 Summary of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³) at Week 48
 - Overall and by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
White	Q4W IM	214	Baseline	214	702.8	253.70	680.5	522.0	827.0	185	1739
			Week 48	182	721.3	269.63	696.0	526.0	885.0	198	1939
			Change	182	19.4	185.73	8.5	-80.0	148.0	-536	801
	Current ART	207	Baseline	207	693.1	288.72	659.0	466.0	875.0	150	1797
			Week 48	196	717.8	288.15	694.0	482.5	903.5	214	1629
			Change	196	17.5	169.22	11.5	-75.0	102.5	-1043	521
Non-White	Q4W IM	94	Baseline	94	623.2	257.62	602.5	439.0	742.0	215	1903
			Week 48	81	604.4	228.99	568.0	467.0	699.0	167	1248
			Change	81	-11.5	190.01	-12.0	-125.0	90.0	-398	621
	Current ART	101	Baseline	101	692.3	290.21	649.0	524.0	810.0	241	2543
			Week 48	94	714.4	303.99	655.5	531.0	854.0	287	2426
			Change	94	23.5	168.74	15.5	-66.0	107.0	-603	460

Note: Summaries at Baseline and Week 48 are actual values, Change represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

11OCT2019 03:44

Table 2.03
 Summary of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³) at Week 48
 - Overall and by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
North America	Q4W IM	93	Baseline	93	742.7	316.83	720.0	508.0	943.0	185	1903
			Week 48	85	702.0	274.79	716.0	502.0	892.0	167	1261
			Change	85	-25.6	182.74	-10.0	-125.0	69.0	-536	455
	Current ART	107	Baseline	107	731.1	309.48	718.0	501.0	877.0	289	2543
			Week 48	98	762.0	328.10	724.5	550.0	912.0	276	2426
			Change	98	23.7	151.07	8.0	-65.0	107.0	-419	439
Europe	Q4W IM	145	Baseline	145	647.2	215.93	612.0	487.0	796.0	266	1398
			Week 48	119	681.9	254.43	638.0	503.0	788.0	307	1939
			Change	119	35.0	182.72	25.0	-68.0	162.0	-474	801
	Current ART	146	Baseline	146	679.8	282.36	643.5	470.0	842.0	150	1797
			Week 48	139	711.0	289.04	688.0	472.0	889.0	214	1629
			Change	139	25.3	158.84	34.0	-74.0	99.0	-498	521
Rest of World	Q4W IM	70	Baseline	70	658.1	234.43	632.5	521.0	793.0	215	1558
			Week 48	59	668.0	265.70	612.0	505.0	789.0	227	1476
			Change	59	10.5	197.34	-7.0	-123.0	109.0	-398	621
	Current ART	55	Baseline	55	652.8	258.61	592.0	495.0	793.0	241	1733
			Week 48	53	647.8	212.94	625.0	476.0	798.0	287	1056
			Change	53	-3.8	219.43	11.0	-77.0	118.0	-1043	460

Note: Summaries at Baseline and Week 48 are actual values, Change represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

11OCT2019 03:44

Table 2.03
 Summary of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³) at Week 48
 - Overall and by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
PI	Q4W IM	51	Baseline	51	615.7	252.00	552.0	428.0	810.0	284	1558
			Week 48	43	600.1	238.02	543.0	439.0	720.0	227	1476
			Change	43	-10.7	116.88	-30.0	-98.0	66.0	-228	224
	Current ART	54	Baseline	54	655.2	254.68	660.5	465.0	812.0	209	1376
			Week 48	50	647.2	259.74	629.0	443.0	798.0	214	1308
			Change	50	-6.7	128.36	-2.5	-79.0	70.0	-366	275
INI	Q4W IM	102	Baseline	102	731.7	288.58	718.5	517.0	905.0	185	1739
			Week 48	91	699.4	277.74	675.0	520.0	892.0	167	1644
			Change	91	-20.6	194.48	-29.0	-130.0	85.0	-536	455
	Current ART	99	Baseline	99	740.1	311.18	708.0	541.0	877.0	150	2543
			Week 48	94	769.8	315.13	736.0	586.0	907.0	217	2426
			Change	94	25.0	191.03	14.0	-65.0	116.0	-1043	521
NNRTI	Q4W IM	155	Baseline	155	664.2	230.57	631.0	512.0	797.0	215	1903
			Week 48	129	703.7	256.53	658.0	520.0	838.0	234	1939
			Change	129	38.4	197.65	30.0	-57.0	135.0	-416	801
	Current ART	155	Baseline	155	675.7	282.89	639.0	445.0	852.0	220	1797
			Week 48	146	706.3	284.33	657.5	472.0	909.0	251	1629
			Change	146	24.8	165.93	15.5	-69.0	114.0	-603	460

Note: Summaries at Baseline and Week 48 are actual values, Change represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

11OCT2019 03:44

Table 2.04
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 - Overall - MMRM - ATLAS

Treatment	N	n	Adjusted		Difference[2] (95% CI)	P-value	Hedges'g		
			Mean[1]	S.E			Hedges'g (S.E)	95% CI	P-value
Q4W IM	308	263	5.72	10.812	-13.34 (-41.40, 14.72)	0.351	-0.0777 (0.08507)	(-0.2448, 0.0894)	0.361
Current ART	308	290	19.06	9.338					

[1] Adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from MMRM with the following covariates/factors: treatment, visit, treatment*visit, baseline CD4+ cell count (cells/mm³), sex at birth (female, male) and baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q4W IM - Current ART.

Note: MMRM = Mixed Model Repeated Measures.

PPD

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS

Subgroup: Age (years) (< 35 vs. >= 35 - < 50 vs. >= 50)
 Category: <35

Treatment	N	n	Adjusted		Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
			Mean[1]	S.E				Hedges'g (S.E)	95% CI	P-value
Q4W IM	80	70	28.63	19.958	19.30 (-35.17, 73.76)	0.487	0.149	0.0583 (0.16545)	(-0.2667, 0.3833)	0.725
Current ART	80	76	9.33	19.386						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, baseline CD4+ cell count (cells/mm³), sex at birth (female, male), baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - Current ART.

[3] Inter = Interaction between each subgroup and treatment.

PPD

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS

Subgroup: Age (years) (< 35 vs. >= 35 - < 50 vs. >= 50)
 Category: 35 - <50

Treatment	N	n	Adjusted		Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
			Mean[1]	S.E				Hedges'g (S.E)	95% CI	P-value
Q4W IM	162	135	20.41	14.160	-9.42 (-50.19, 31.36)	0.650	0.149	-0.0377 (0.12449)	(-0.2822, 0.2068)	0.762
Current ART	132	123	29.83	15.174						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, baseline CD4+ cell count (cells/mm³), sex at birth (female, male), baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - Current ART.

[3] Inter = Interaction between each subgroup and treatment.

PPD

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS

Subgroup: Age (years) (< 35 vs. >= 35 - < 50 vs. >= 50)
 Category: >=50

Treatment	N	n	Adjusted		Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
			Mean[1]	S.E				Hedges'g (S.E)	95% CI	P-value
Q4W IM	66	58	-51.81	21.879	-64.04 (-119.19, -8.89)	0.023	0.149	-0.1953 (0.16790)	(-0.5250, 0.1345)	0.245
Current ART	96	91	12.23	17.639						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, baseline CD4+ cell count (cells/mm³), sex at birth (female, male), baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - Current ART.

[3] Inter = Interaction between each subgroup and treatment.

PPD

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS

Subgroup: Sex at Birth (Female vs. Male)
 Category: Female

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	99	86	25.68	18.021	3.76 (-44.96, 52.48)	0.879	0.925	0.0127 (0.14792)	(-0.2779, 0.3032)	0.932
Current ART	104	97	21.92	17.199						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, baseline CD4+ cell count (cells/mm³), sex at birth (female, male), baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - Current ART.

[3] Inter = Interaction between each subgroup and treatment.

PPD

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS

Subgroup: Sex at Birth (Female vs. Male)
 Category: Male

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	209	177	-2.44	12.482	-20.00 (-54.15, 14.15)	0.250	0.925	-0.0958 (0.10398)	(-0.3001, 0.1084)	0.357
Current ART	204	193	17.56	12.161						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, baseline CD4+ cell count (cells/mm³), sex at birth (female, male), baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - Current ART.

[3] Inter = Interaction between each subgroup and treatment.

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS

Subgroup: Race (White vs. Non-White)
 Category: White

Treatment	N	n	Adjusted		Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
			Mean[1]	S.E				Hedges'g (S.E)	95% CI	P-value
Q4W IM	214	182	23.07	12.297	2.81 (-30.85, 36.46)	0.870	0.324	0.0137 (0.10281)	(-0.1883, 0.2156)	0.894
Current ART	207	196	20.26	12.029						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, baseline CD4+ cell count (cells/mm³), sex at birth (female, male), baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - Current ART.

[3] Inter = Interaction between each subgroup and treatment.

PPD

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS

Subgroup: Race (White vs. Non-White)
 Category: Non-White

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	94	81	-30.28	18.579	-46.95 (-96.58, 2.68)	0.064	0.324	-0.1550 (0.15148)	(-0.4525, 0.1425)	0.307
Current ART	101	94	16.67	17.413						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, baseline CD4+ cell count (cells/mm³), sex at birth (female, male), baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - Current ART.

[3] Inter = Interaction between each subgroup and treatment.

PPD

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)
 Category: North America

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	93	85	-31.10	18.466	-54.79 (-103.53, -6.05)	0.028	0.025	-0.1853 (0.14813)	(-0.4763, 0.1056)	0.211
Current ART	107	98	23.69	17.215						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, baseline CD4+ cell count (cells/mm³), sex at birth (female, male), baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - Current ART.

[3] Inter = Interaction between each subgroup and treatment.

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)
 Category: Europe

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	145	119	31.40	15.095	4.03 (-36.75, 44.82)	0.846	0.025	0.0162 (0.12473)	(-0.2288, 0.2611)	0.897
Current ART	146	139	27.37	14.374						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, baseline CD4+ cell count (cells/mm³), sex at birth (female, male), baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - Current ART.

[3] Inter = Interaction between each subgroup and treatment.

PPD

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)
 Category: Rest of World

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	70	59	7.19	21.672	19.56 (-42.58, 81.69)	0.537	0.025	0.0517 (0.18901)	(-0.3195, 0.4230)	0.784
Current ART	55	53	-12.36	23.377						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, baseline CD4+ cell count (cells/mm³), sex at birth (female, male), baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - Current ART.

[3] Inter = Interaction between each subgroup and treatment.

PPD

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)
 Category: PI

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	51	43	-33.21	25.269	-16.43 (-84.44, 51.59)	0.635	0.767	-0.0395 (0.20771)	(-0.4475, 0.3685)	0.849
Current ART	54	50	-16.78	23.815						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, baseline CD4+ cell count (cells/mm³), sex at birth (female, male), baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - Current ART.

[3] Inter = Interaction between each subgroup and treatment.

PPD

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)
 Category: INI

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Q4W IM	102	91	-14.56	17.603	-46.71 (-95.13, 1.71)	0.059	0.767	-0.1586 (0.14694)	(-0.4473, 0.1300)	0.281
Current ART	99	94	32.15	17.455						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, baseline CD4+ cell count (cells/mm³), sex at birth (female, male), baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - Current ART.

[3] Inter = Interaction between each subgroup and treatment.

PPD

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)
 Category: NNRTI

Treatment	N	n	Adjusted		Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges'g		
			Mean[1]	S.E				Hedges'g (S.E)	95% CI	P-value
Q4W IM	155	129	35.51	14.505	13.00 (-26.48, 52.48)	0.518	0.767	0.0537 (0.12069)	(-0.1833, 0.2908)	0.656
Current ART	155	146	22.52	13.939						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline at Week 48 in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (include if subgroup = age, race or region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, baseline CD4+ cell count (cells/mm³), sex at birth (female, male), baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured. MMRM = Mixed Model Repeated Measures.

[2] Difference: Q4W IM - Current ART.

[3] Inter = Interaction between each subgroup and treatment.

PPD

Table 3.26
 Analysis of Proportion of Subjects with any New Onset of an "HIV-infection stage 3"
 Event (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Overall

Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall	1/308 (<1%)	0/308	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC	

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.26
 Analysis of Proportion of Subjects with any New Onset of an "HIV-infection stage 3"
 Event (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
<35	0/80	0/80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/66	0/96	NC	NC	NC	

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.26
 Analysis of Proportion of Subjects with any New Onset of an "HIV-infection stage 3"
 Event (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Female	0/99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.26
 Analysis of Proportion of Subjects with any New Onset of an "HIV-infection stage 3"
 Event (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/94	0/101	NC	NC	NC	

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.26
 Analysis of Proportion of Subjects with any New Onset of an "HIV-infection stage 3"
 Event (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
North America	0/93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/70	0/55	NC	NC	NC	

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.26
 Analysis of Proportion of Subjects with any New Onset of an "HIV-infection stage 3"
 Event (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
PI	0/51	0/54	NC	NC	NC	NC
INI	0/102	0/99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 7.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Domain: Mental Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Overall	Overall	Q4W IM	308	Baseline	301	53.129	8.1897	55.010	49.490	58.110	20.99	64.98	
				Week 24	296	53.488	8.5867	55.325	48.550	60.070	25.16	77.40	
				Week 48	281	53.801	8.8383	55.810	49.980	60.160	17.41	71.96	
				W48 CFB	275	0.511	8.8633	0.000	-2.790	4.440	-31.92	30.44	
		Current ART	308	Baseline	297	53.677	7.3377	55.060	49.920	58.050	25.89	71.93	
				Week 24	296	53.433	8.5827	55.200	48.890	60.070	16.09	64.47	
				Week 48	296	53.565	8.0436	55.730	49.245	59.505	17.01	68.18	
				W48 CFB	286	-0.447	8.2190	0.000	-4.780	3.660	-32.65	26.62	
Age (years) <35	Q4W IM	80	Baseline	78	53.568	7.8573	55.220	49.940	60.070	30.26	64.72		
			Week 24	75	52.533	9.0797	55.120	45.530	59.690	25.16	66.10		
			Week 48	72	53.233	9.2171	55.045	49.060	60.070	20.49	67.82		
			W48 CFB	70	-0.828	8.4742	-0.540	-3.040	2.530	-24.16	28.60		
			Current ART	80	Baseline	77	52.576	6.7754	54.750	47.980	57.380	30.98	62.48
					Week 24	76	52.518	8.8254	54.590	48.095	57.700	20.84	64.26
	Week 48	77			52.468	7.8944	53.840	47.590	57.380	33.34	62.38		
	W48 CFB	75			-0.222	8.4132	0.000	-5.200	5.000	-20.97	21.65		
	35 - <50	Q4W IM	162	Baseline	158	53.538	7.8523	55.030	50.820	58.110	20.99	64.98	
				Week 24	155	54.433	7.8740	57.280	49.920	61.210	29.35	65.71	
				Week 48	146	54.466	8.8883	57.280	51.120	62.130	17.41	71.96	
				W48 CFB	143	0.720	9.4846	1.210	-2.790	5.000	-31.92	30.44	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:51

Table 7.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Domain: Mental Component Score

Subgroup	Category	Treatment	N	Actual Relative		Mean	SD	Median	Q1	Q3	Min.	Max.
				Time	n							
Age (years)	35 - <50	Current ART	132	Baseline	127	53.339	8.1284	55.640	49.660	58.120	25.89	64.44
				Week 24	127	52.643	9.2211	55.060	47.460	59.600	16.09	64.47
				Week 48	127	53.803	8.3854	56.720	49.490	59.690	17.01	68.16
				W48 CFB	122	-0.132	8.3421	-0.075	-5.050	3.040	-32.65	26.62
	>=50	Q4W IM	66	Baseline	65	51.607	9.2661	54.590	46.960	57.820	27.14	64.13
				Week 24	66	52.352	9.4545	54.545	46.770	58.420	27.62	77.40
				Week 48	63	52.908	8.2768	55.270	49.020	58.250	27.69	65.93
				W48 CFB	62	1.540	7.6806	0.285	-2.390	5.090	-27.12	22.69
		Current ART	96	Baseline	93	55.050	6.4610	55.340	52.130	60.070	38.68	71.93
				Week 24	93	55.260	7.1645	57.280	51.800	60.390	25.19	63.97
				Week 48	92	54.154	7.6737	57.205	49.580	59.600	30.04	68.18
				W48 CFB	89	-1.069	7.9369	-0.250	-4.650	2.980	-29.16	17.89
Sex at birth	Female	Q4W IM	99	Baseline	96	53.070	8.5265	55.370	49.205	58.345	27.14	64.72
				Week 24	97	55.379	8.8119	57.530	52.120	62.380	27.62	77.40
				Week 48	91	55.010	9.1717	57.380	51.270	62.380	17.41	71.96
				W48 CFB	89	1.859	8.0005	1.670	-2.340	6.570	-26.89	22.69
		Current ART	104	Baseline	99	53.393	7.6846	55.060	49.170	58.050	29.62	71.93
				Week 24	98	53.597	8.9088	57.380	48.720	60.160	25.22	64.26
				Week 48	100	53.818	7.9957	55.785	49.580	58.420	17.01	68.18
				W48 CFB	95	-0.103	8.9528	0.000	-5.910	5.000	-32.65	21.65

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:51

Table 7.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Domain: Mental Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Sex at birth	Male	Q4W IM	209	Baseline	205	53.156	8.0483	54.750	49.940	58.050	20.99	64.98
				Week 24	199	52.566	8.3426	54.590	47.690	58.050	25.16	66.10
				Week 48	190	53.222	8.6388	55.060	49.760	59.600	20.49	63.36
				W48 CFB	186	-0.134	9.1985	0.000	-2.840	3.600	-31.92	30.44
	Current ART	204	Baseline	198	53.819	7.1738	55.060	50.230	58.270	25.89	64.44	
			Week 24	198	53.352	8.4385	54.970	49.490	59.600	16.09	64.47	
			Week 48	196	53.435	8.0853	55.415	48.350	59.600	29.87	68.16	
			W48 CFB	191	-0.618	7.8476	-0.100	-4.480	2.780	-29.16	26.62	
Race	White	Q4W IM	214	Baseline	211	52.738	8.2601	54.750	49.640	57.530	20.99	64.98
				Week 24	207	52.794	8.1040	54.590	48.490	57.900	25.16	65.71
				Week 48	197	52.496	8.8438	54.590	49.390	57.900	17.41	71.96
				W48 CFB	194	-0.292	8.9560	0.000	-3.410	3.570	-31.92	30.44
	Current ART	207	Baseline	203	53.365	7.4000	55.030	49.500	57.800	25.89	64.12	
			Week 24	201	53.074	8.1876	54.750	48.890	58.420	16.09	63.97	
			Week 48	198	53.347	7.8524	55.460	49.490	58.160	29.87	68.18	
			W48 CFB	195	-0.194	7.6809	-0.090	-4.480	3.020	-20.97	26.62	
Non-White	Q4W IM	94	Baseline	90	54.044	7.9924	55.585	49.160	60.160	27.14	64.72	
			Week 24	89	55.100	9.4695	58.340	49.920	62.380	29.35	77.40	
			Week 48	84	56.862	8.0809	60.115	54.355	62.380	20.49	67.82	
			W48 CFB	81	2.434	8.3816	2.510	-0.750	6.570	-26.89	22.69	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:51

Table 7.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Domain: Mental Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.		
Race	Non-White	Current ART	101	Baseline	94	54.351	7.1942	55.130	49.920	59.600	29.62	71.93		
				Week 24	95	54.192	9.3641	57.530	48.630	62.380	25.22	64.47		
				Week 48	98	54.004	8.4409	56.950	49.020	60.480	17.01	65.89		
				W48 CFB	91	-0.988	9.2904	1.040	-5.620	4.020	-32.65	19.01		
Region	North America	Q4W IM	93	Baseline	91	54.170	7.9841	55.220	51.240	59.690	20.99	64.98		
				Week 24	90	53.131	9.1306	55.090	48.140	59.600	25.16	77.40		
				Week 48	87	53.162	9.0174	55.060	49.960	60.070	20.49	63.26		
				W48 CFB	86	-1.137	7.6675	-0.730	-2.840	2.690	-27.12	30.25		
				Current ART	107	Baseline	106	53.609	7.2259	55.025	50.230	57.380	29.62	66.38
						Week 24	105	51.212	10.0725	54.380	46.810	58.160	16.09	63.96
	Week 48	101	53.017			7.6067	54.590	47.760	58.270	30.04	68.16			
	W48 CFB	101	-1.214			6.7467	-0.150	-5.050	2.320	-19.13	19.01			
	Europe	Q4W IM	145			Baseline	140	53.065	7.7188	54.590	49.530	57.835	28.07	64.98
						Week 24	140	53.736	7.4015	54.590	49.020	59.600	31.79	65.71
				Week 48	132	53.404	8.5237	54.670	49.785	59.600	17.41	71.96		
				W48 CFB	127	0.295	8.8371	0.000	-3.410	4.570	-31.92	28.60		
Current ART				146	Baseline	141	53.725	7.1569	55.110	49.410	58.730	30.98	63.97	
					Week 24	140	53.997	7.1287	54.980	50.135	59.190	27.54	63.97	
	Week 48	140	53.795		8.1836	56.965	50.280	59.355	17.01	68.18				
	W48 CFB	135	0.036		8.5461	-0.100	-4.130	5.010	-32.65	26.62				

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:51

Table 7.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Domain: Mental Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	Rest of World	Q4W IM	70	Baseline	70	51.901	9.2452	54.710	45.490	59.690	27.14	63.36	
				Week 24	66	53.448	10.1498	57.380	47.880	62.380	29.35	64.46	
				Week 48	62	55.544	9.1592	57.855	51.270	62.380	26.60	67.82	
				W48 CFB	62	3.240	9.9064	2.735	-0.250	8.110	-29.04	30.44	
	Current ART	55	Baseline	50	53.685	8.1854	54.905	50.000	58.640	25.89	71.93		
			Week 24	51	56.460	7.8554	60.160	51.960	62.380	32.84	64.47		
			Week 48	55	53.985	8.5458	57.280	47.780	62.380	29.87	65.89		
			W48 CFB	50	-0.201	9.9178	2.215	-6.030	4.850	-29.16	17.89		
	Baseline third agent class	PI	Q4W IM	51	Baseline	51	53.237	8.1468	55.220	50.630	58.050	30.49	64.72
					Week 24	51	53.350	9.6789	57.280	47.690	60.950	29.35	62.63
					Week 48	47	53.506	8.9802	57.280	49.780	60.070	22.58	62.48
					W48 CFB	47	0.052	7.8510	0.000	-3.410	5.090	-31.92	13.49
Current ART		54	Baseline	50	52.907	7.2607	54.750	46.780	57.530	29.62	62.65		
			Week 24	52	54.519	6.2750	56.945	49.265	59.700	39.06	63.00		
			Week 48	52	53.847	7.1711	57.280	49.670	58.415	30.70	62.48		
			W48 CFB	48	0.388	8.2666	0.045	-4.860	5.910	-19.15	13.71		
INI		Q4W IM	102	Baseline	100	52.752	8.2553	55.020	48.940	57.385	28.07	64.98	
				Week 24	99	52.371	8.8367	55.060	47.520	58.050	25.16	65.71	
				Week 48	95	52.740	9.5183	55.060	48.860	59.600	20.49	71.96	
				W48 CFB	93	-0.398	8.5180	0.000	-2.780	3.960	-27.12	18.41	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:51

Table 7.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Domain: Mental Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Baseline third agent class	INI	Current ART	99	Baseline	98	53.482	7.0882	55.060	49.410	57.530	25.89	64.12
				Week 24	97	52.389	8.7401	54.590	47.450	59.190	25.19	63.96
				Week 48	97	53.281	7.2752	54.590	48.110	57.900	29.87	68.16
				W48 CFB	97	-0.274	7.1914	0.000	-4.130	2.410	-19.13	20.16
				Baseline	150	53.343	8.2063	54.630	49.490	59.690	20.99	64.29
				Week 24	146	54.293	7.9633	55.045	49.020	60.160	29.44	77.40
	NNRTI	Q4W IM	155	Baseline	150	53.343	8.2063	54.630	49.490	59.690	20.99	64.29
				Week 24	146	54.293	7.9633	55.045	49.020	60.160	29.44	77.40
				Week 48	139	54.625	8.2713	55.740	50.700	62.380	17.41	67.82
				W48 CFB	135	1.297	9.4016	0.000	-2.780	5.970	-29.04	30.44
				Baseline	155	54.063	7.5449	55.140	50.500	58.730	30.98	71.93
				Week 24	147	53.738	9.1443	55.620	49.980	60.390	16.09	64.47
	Week 48	147	53.652	8.8246	57.270	49.490	60.160	17.01	68.18			
	W48 CFB	141	-0.850	8.8707	-0.250	-5.200	3.040	-32.65	26.62			

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:51

Table 7.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Domain: Physical Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Overall	Overall	Q4W IM	308	Baseline	298	55.239	5.7354	56.910	54.350	58.380	27.80	71.51	
				Week 24	296	55.752	5.5517	57.340	54.640	58.600	19.44	64.98	
				Week 48	281	55.917	5.5057	57.410	54.920	58.600	24.45	69.84	
				W48 CFB	272	0.807	5.4194	0.250	-1.385	3.330	-21.58	23.46	
		Current ART	308	Baseline	299	54.611	5.7577	56.480	53.650	57.620	27.97	64.91	
				Week 24	296	54.660	5.9611	57.120	52.770	58.105	31.02	66.76	
				Week 48	296	54.835	6.2382	57.120	53.150	58.380	25.33	67.19	
				W48 CFB	288	0.112	5.7679	0.280	-2.320	2.470	-32.01	28.99	
Age (years) <35	Q4W IM	80	Baseline	78	56.313	4.2071	57.615	54.640	58.600	42.20	63.62		
			Week 24	75	57.214	3.2446	57.620	55.850	58.890	46.54	64.53		
			Week 48	72	57.681	3.4928	57.620	56.920	59.030	45.20	65.13		
			W48 CFB	70	1.448	4.7394	0.740	-0.980	4.020	-12.94	16.40		
			Current ART	80	Baseline	78	56.602	3.4797	57.120	55.350	58.320	40.46	64.91
					Week 24	76	56.696	4.7077	57.620	55.920	58.745	39.02	66.41
	Week 48	77			57.214	3.0858	57.620	56.410	59.110	46.16	62.63		
	W48 CFB	76			0.624	3.9176	0.505	-1.675	2.500	-9.78	17.16		
	35 - <50	Q4W IM	162	Baseline	155	55.593	5.3748	56.700	54.650	58.380	35.47	71.51	
				Week 24	155	56.176	4.3134	57.520	55.040	58.600	37.65	64.76	
				Week 48	146	55.998	5.2244	57.620	55.130	58.380	24.45	69.84	
				W48 CFB	140	0.511	5.2267	0.310	-1.770	2.755	-20.53	23.46	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:51

Table 7.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Domain: Physical Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Age (years)	35 - <50	Current ART	132	Baseline	128	54.884	5.0197	56.480	53.650	57.340	27.97	63.22
				Week 24	127	54.129	5.9909	55.900	51.850	57.620	35.74	66.76
				Week 48	127	54.454	6.5716	56.850	52.720	58.170	25.39	67.19
				W48 CFB	123	-0.545	5.4903	0.120	-2.480	2.110	-19.15	18.87
	>=50	Q4W IM	66	Baseline	65	53.104	7.4500	55.850	49.960	58.380	27.80	65.62
				Week 24	66	53.095	8.5878	56.480	51.280	57.620	19.44	64.98
				Week 48	63	53.712	7.1079	55.850	52.540	57.620	26.05	60.94
				W48 CFB	62	0.751	6.4921	0.000	-1.770	3.470	-21.58	17.28
		Current ART	96	Baseline	93	52.564	7.4002	54.920	49.340	57.620	28.63	61.06
				Week 24	93	53.722	6.4822	56.250	50.310	57.620	31.02	61.87
				Week 48	92	53.369	7.1580	55.685	50.735	57.620	25.33	65.46
				W48 CFB	89	0.584	7.2509	0.000	-2.860	2.670	-32.01	28.99
Sex at birth	Female	Q4W IM	99	Baseline	96	54.200	6.3237	56.175	52.800	57.740	35.47	65.49
				Week 24	97	55.042	6.4439	57.410	54.430	57.960	19.44	64.76
				Week 48	91	54.711	6.3094	57.120	52.670	57.620	24.45	64.97
				W48 CFB	89	0.655	6.9123	0.930	-1.770	3.750	-21.58	17.28
		Current ART	104	Baseline	100	53.280	7.0768	55.900	50.680	57.340	28.63	63.22
				Week 24	98	53.143	6.2367	55.820	50.050	57.400	35.67	66.76
				Week 48	100	53.425	7.8365	56.130	51.855	57.855	25.33	62.69
				W48 CFB	96	-0.062	7.8221	0.380	-3.475	2.540	-32.01	28.99

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:51

Table 7.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Domain: Physical Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Sex at birth	Male	Q4W IM	209	Baseline	202	55.732	5.3801	57.120	54.700	58.510	27.80	71.51
				Week 24	199	56.098	5.0419	57.340	55.030	58.600	30.40	64.98
				Week 48	190	56.494	4.9916	57.620	55.850	58.890	26.05	69.84
				W48 CFB	183	0.881	4.5401	0.220	-1.270	2.760	-12.88	23.46
	Current ART	204	Baseline	199	55.279	4.8487	56.830	54.140	57.820	27.97	64.91	
			Week 24	198	55.411	5.6876	57.340	54.000	58.450	31.02	66.41	
			Week 48	196	55.554	5.1141	57.120	53.850	58.535	30.91	67.19	
			W48 CFB	192	0.199	4.4198	0.280	-1.990	2.440	-14.87	18.87	
Race	White	Q4W IM	214	Baseline	209	55.274	5.7937	56.890	54.480	58.380	27.80	71.51
				Week 24	207	56.018	5.1458	57.340	54.640	58.600	28.08	64.98
				Week 48	197	56.306	5.3767	57.580	55.630	58.890	24.45	69.84
				W48 CFB	192	1.241	4.9735	0.605	-0.990	3.500	-20.53	23.46
	Current ART	207	Baseline	205	55.082	5.5880	56.900	54.140	57.900	27.97	64.91	
			Week 24	201	55.186	5.4920	57.120	53.370	58.380	35.67	66.41	
			Week 48	198	55.154	5.9209	57.120	53.150	58.460	25.39	67.19	
			W48 CFB	197	0.001	5.3699	0.000	-2.190	2.200	-19.15	28.99	
Non-White	Q4W IM	94	Baseline	89	55.156	5.6275	57.120	53.650	58.380	34.71	63.62	
			Week 24	89	55.134	6.3862	57.450	54.640	57.620	19.44	62.60	
			Week 48	84	55.003	5.7260	57.300	52.795	57.620	26.05	64.97	
			W48 CFB	80	-0.234	6.2763	0.000	-3.105	2.580	-21.58	17.28	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:51

Table 7.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Domain: Physical Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.		
Race	Non-White	Current ART	101	Baseline	94	53.582	6.0142	55.735	51.230	57.340	29.23	61.20		
				Week 24	95	53.547	6.7456	56.140	50.050	57.620	31.02	66.76		
				Week 48	98	54.189	6.8207	56.385	52.720	57.620	25.33	62.69		
				W48 CFB	91	0.353	6.5731	1.200	-2.450	2.930	-32.01	25.50		
Region	North America	Q4W IM	93	Baseline	91	55.610	6.4463	57.620	54.770	58.600	27.80	71.51		
				Week 24	90	55.788	6.6057	57.480	54.760	58.670	19.44	64.53		
				Week 48	87	56.240	5.8650	57.620	55.900	58.600	24.45	65.13		
				W48 CFB	86	0.740	4.9482	0.000	-1.270	2.480	-12.94	16.40		
				Current ART	107	Baseline	106	54.399	6.3331	57.120	52.800	58.100	32.62	64.91
						Week 24	105	54.167	7.0173	57.120	50.050	58.460	33.73	66.76
	Week 48	101	54.146			7.8189	57.120	52.770	58.460	25.33	61.93			
	W48 CFB	101	-0.432			5.9566	0.000	-2.280	1.770	-32.01	14.92			
	Europe	Q4W IM	145	Baseline	137	55.285	5.3131	56.700	54.430	58.440	35.86	65.49		
				Week 24	140	56.022	4.6264	57.400	54.640	58.425	35.35	64.98		
				Week 48	132	56.310	4.7043	57.370	54.925	58.890	34.36	69.84		
				W48 CFB	124	1.228	5.3634	0.605	-1.195	3.495	-20.53	23.46		
Current ART				146	Baseline	143	55.290	4.9065	56.520	54.200	57.620	27.97	64.27	
					Week 24	140	55.367	4.6586	56.940	53.655	57.790	39.02	66.25	
	Week 48	140	55.441		5.1109	57.120	53.540	58.550	36.35	67.19				
	W48 CFB	137	0.076		5.6760	0.280	-2.270	2.470	-19.15	28.99				

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:51

Table 7.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Domain: Physical Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	Rest of World	Q4W IM	70	Baseline	70	54.665	5.5882	56.130	53.650	57.620	34.71	62.73	
				Week 24	66	55.132	5.8151	57.120	54.540	57.620	30.40	64.76	
				Week 48	62	54.626	6.3986	57.120	53.780	57.620	26.05	61.79	
				W48 CFB	62	0.058	6.1173	-0.160	-2.820	3.730	-21.58	17.28	
	Current ART	55	Baseline	50	53.116	6.4943	54.625	49.540	57.120	29.23	63.22		
			Week 24	51	53.736	6.6419	56.200	50.290	57.620	31.02	63.48		
			Week 48	55	54.557	5.4973	56.360	51.770	57.620	35.95	65.46		
			W48 CFB	50	1.311	5.5633	1.510	-2.600	3.970	-8.58	25.50		
	Baseline third agent class	PI	Q4W IM	51	Baseline	51	54.783	5.8311	56.160	54.480	57.620	34.71	60.45
					Week 24	51	55.932	5.4818	57.620	54.640	58.380	30.40	64.76
					Week 48	47	55.000	8.3964	57.340	55.850	58.890	24.45	69.84
					W48 CFB	47	0.402	5.2286	0.220	-1.270	4.240	-12.88	9.97
Current ART		54	Baseline	51	54.415	4.6292	55.900	52.870	57.340	39.80	60.55		
			Week 24	52	52.761	6.1812	54.640	51.540	57.145	31.02	59.62		
			Week 48	52	53.802	6.8918	56.130	52.820	57.620	25.33	61.62		
			W48 CFB	49	-1.072	6.7379	0.000	-2.480	2.970	-32.01	7.91		
INI		Q4W IM	102	Baseline	97	55.038	6.3220	57.120	54.350	58.510	27.80	65.62	
				Week 24	99	56.031	5.4269	57.120	55.520	58.600	28.08	64.53	
				Week 48	95	56.281	5.2846	57.620	56.130	58.600	34.23	64.97	
				W48 CFB	90	1.390	4.5669	0.285	-1.090	3.470	-12.94	16.40	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:51

Table 7.01
 Summary of SF-12 in MCS and PCS Scores by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Domain: Physical Component Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Baseline third agent class	INI	Current ART	99	Baseline	98	55.111	5.1545	57.120	54.350	57.900	35.29	61.71
				Week 24	97	55.051	5.9573	57.120	53.220	58.600	35.74	66.76
				Week 48	97	54.688	6.3408	57.120	52.290	58.500	25.39	61.93
				W48 CFB	97	-0.545	4.5625	0.000	-2.280	1.770	-17.84	14.87
	NNRTI	Q4W IM	155	Baseline	150	55.523	5.3130	57.020	53.650	58.380	36.21	71.51
				Week 24	146	55.501	5.6842	57.425	54.130	58.600	19.44	64.98
				Week 48	139	55.978	4.3128	57.340	54.640	58.380	35.82	63.89
				W48 CFB	135	0.559	5.9843	0.150	-1.710	2.760	-21.58	23.46
		Current ART	155	Baseline	150	54.350	6.4474	56.130	53.400	57.620	27.97	64.91
				Week 24	147	55.074	5.7930	57.120	52.840	58.380	33.73	66.41
				Week 48	147	55.297	5.9154	57.120	53.880	58.460	29.12	67.19
				W48 CFB	142	0.970	6.0469	0.620	-2.270	2.670	-17.32	28.99

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:51

Table 7.02
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores at
 Week 48 - Overall - MMRM - ATLAS

Domain: Mental Component Score

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q4W IM	308	275	0.30	0.469	0.66 (-0.60, 1.93)	0.305	0.0874 (0.08438)	(-0.0784, 0.2531)	0.301
Current ART	308	286	-0.36	0.441					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, treatment*visit, Maintenance BL (Day 1) Score, sex at birth (female, male), age (<50, >= 50 years), race (white, non-white) and Baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor.

No assumptions were made about the correlations between subject readings of SF12 scores, i.e., the correlation matrix for within-subject errors is unstructured.

[2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

PPD

Table 7.02
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores at
 Week 48 - Overall - MMRM - ATLAS

Domain: Physical Component Score

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q4W IM	308	272	0.85	0.277	0.79 (-0.03, 1.60)	0.059	0.1597 (0.08457)	(-0.0064, 0.3258)	0.060
Current ART	308	288	0.06	0.309					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, treatment*visit, Maintenance BL (Day 1) Score, sex at birth (female, male), age (<50, >= 50 years), race (white, non-white) and Baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor.

No assumptions were made about the correlations between subject readings of SF12 scores, i.e., the correlation matrix for within-subject errors is unstructured.

[2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

PPD

Table 7.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores
 at Week 48 by Subgroup - MMRM - ATLAS

Domain: Mental Component Score
 Subgroup: Age (years) (< 35 vs. >= 35 - < 50 vs. >= 50)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<35	Q4W IM	80	70	-0.37 (0.933)	0.12 (-2.38, 2.61)	0.927	0.374	0.0079 (0.16596)	(-0.3181, 0.3339)	0.962
	Current ART	80	75	-0.49 (0.869)						
35 - <50	Q4W IM	162	143	0.62 (0.651)	0.88 (-0.97, 2.73)	0.351	0.374	0.0798 (0.12310)	(-0.1620, 0.3216)	0.517
	Current ART	132	122	-0.26 (0.678)						
>=50	Q4W IM	66	62	0.29 (0.994)	0.66 (-1.84, 3.17)	0.602	0.374	0.0463 (0.16519)	(-0.2782, 0.3708)	0.779
	Current ART	96	89	-0.37 (0.793)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF12 scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores
 at Week 48 by Subgroup - MMRM - ATLAS

Domain: Mental Component Score
 Subgroup: Sex at Birth (Female vs. Male)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
Female	Q4W IM	99	89	1.21 (0.837)	1.37 (-0.84, 3.58)	0.223	0.143	0.1044 (0.14735)	(-0.1851, 0.3938)	0.479
	Current ART	104	95	-0.17 (0.777)						
Male	Q4W IM	209	186	-0.13 (0.577)	0.31 (-1.23, 1.86)	0.693	0.143	0.0337 (0.10288)	(-0.1684, 0.2358)	0.744
	Current ART	204	191	-0.45 (0.542)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF12 scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores
 at Week 48 by Subgroup - MMRM - ATLAS

Domain: Mental Component Score
 Subgroup: Race (White vs. Non-White)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
White	Q4W IM	214	194	-0.51 (0.558)	-0.29 (-1.80, 1.22)	0.705	0.075	-0.0322 (0.10127)	(-0.2311, 0.1667)	0.750
	Current ART	207	195	-0.21 (0.535)						
Non-White	Q4W IM	94	81	2.22 (0.866)	2.86 (0.58, 5.13)	0.014	0.075	0.2114 (0.15268)	(-0.0885, 0.5113)	0.167
	Current ART	101	91	-0.64 (0.790)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF12 scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores
 at Week 48 by Subgroup - MMRM - ATLAS

Domain: Mental Component Score
 Subgroup: Region (North America vs. Europe vs. Rest of World)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
North America	Q4W IM	93	86	-0.83 (0.861)	0.22 (-1.98, 2.43)	0.842	0.732	0.0173 (0.14652)	(-0.2706, 0.3051)	0.906
	Current ART	107	101	-1.05 (0.764)						
Europe	Q4W IM	145	127	0.34 (0.714)	-0.02 (-1.86, 1.82)	0.984	0.732	-0.0017 (0.12345)	(-0.2442, 0.2407)	0.989
	Current ART	146	135	0.36 (0.666)						
Rest of World	Q4W IM	70	62	1.83 (1.027)	2.73 (-0.11, 5.58)	0.060	0.732	0.1617 (0.18988)	(-0.2113, 0.5347)	0.395
	Current ART	55	50	-0.90 (1.130)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF12 scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores
 at Week 48 by Subgroup - MMRM - ATLAS

Domain: Mental Component Score
 Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
PI	Q4W IM	51	47	-0.35 (1.135)	-0.65 (-3.71, 2.41)	0.677	0.256	-0.0354 (0.20493)	(-0.4380, 0.3671)	0.863
	Current ART	54	48	0.30 (1.078)						
INI	Q4W IM	102	93	-0.54 (0.812)	-0.33 (-2.50, 1.85)	0.768	0.256	-0.0253 (0.14493)	(-0.3099, 0.2594)	0.862
	Current ART	99	97	-0.22 (0.760)						
NNRTI	Q4W IM	155	135	1.12 (0.671)	1.81 (0.00, 3.62)	0.050	0.256	0.1676 (0.12036)	(-0.0688, 0.4040)	0.164
	Current ART	155	141	-0.69 (0.630)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF12 scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores
 at Week 48 by Subgroup - MMRM - ATLAS

Domain: Physical Component Score
 Subgroup: Age (years) (< 35 vs. >= 35 - < 50 vs. >= 50)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<35	Q4W IM	80	70	2.10 (0.547)	0.71 (-0.87, 2.30)	0.378	0.140	0.0749 (0.16545)	(-0.2501, 0.3999)	0.651
	Current ART	80	76	1.38 (0.602)						
35 - <50	Q4W IM	162	140	0.79 (0.385)	1.23 (0.03, 2.42)	0.044	0.140	0.1732 (0.12352)	(-0.0694, 0.4159)	0.161
	Current ART	132	123	-0.43 (0.471)						
>=50	Q4W IM	66	62	-0.24 (0.581)	0.28 (-1.28, 1.85)	0.722	0.140	0.0307 (0.16520)	(-0.2938, 0.3552)	0.853
	Current ART	96	89	-0.53 (0.555)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF12 scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores
 at Week 48 by Subgroup - MMRM - ATLAS

Domain: Physical Component Score
 Subgroup: Sex at Birth (Female vs. Male)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
Female	Q4W IM	99	89	0.50 (0.493)	1.05 (-0.36, 2.47)	0.145	0.301	0.1236 (0.14700)	(-0.1651, 0.4124)	0.401
	Current ART	104	96	-0.56 (0.544)						
Male	Q4W IM	209	183	1.02 (0.343)	0.65 (-0.35, 1.65)	0.201	0.301	0.1083 (0.10322)	(-0.0944, 0.3111)	0.294
	Current ART	204	192	0.37 (0.380)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF12 scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores
 at Week 48 by Subgroup - MMRM - ATLAS

Domain: Physical Component Score
 Subgroup: Race (White vs. Non-White)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
White	Q4W IM	214	192	1.24 (0.332)	1.07 (0.09, 2.05)	0.032	0.683	0.1817 (0.10142)	(-0.0175, 0.3809)	0.074
	Current ART	207	197	0.17 (0.374)						
Non-White	Q4W IM	94	80	-0.07 (0.518)	0.14 (-1.34, 1.62)	0.850	0.683	0.0160 (0.15306)	(-0.2846, 0.3166)	0.917
	Current ART	101	91	-0.21 (0.555)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF12 scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores
 at Week 48 by Subgroup - MMRM - ATLAS

Domain: Physical Component Score
 Subgroup: Region (North America vs. Europe vs. Rest of World)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
North America	Q4W IM	93	86	0.88 (0.510)	1.49 (0.08, 2.91)	0.038	0.372	0.1761 (0.14662)	(-0.1119, 0.4641)	0.230
	Current ART	107	101	-0.61 (0.533)						
Europe	Q4W IM	145	124	1.18 (0.431)	1.01 (-0.18, 2.20)	0.096	0.372	0.1414 (0.12386)	(-0.1019, 0.3846)	0.254
	Current ART	146	137	0.16 (0.461)						
Rest of World	Q4W IM	70	62	0.15 (0.609)	-0.98 (-2.83, 0.88)	0.302	0.372	-0.0897 (0.18983)	(-0.4626, 0.2832)	0.637
	Current ART	55	50	1.13 (0.783)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF12 scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.03
 Statistical Analysis of SF-12 - Change from Maintenance Baseline in MCS and PCS Scores
 at Week 48 by Subgroup - MMRM - ATLAS

Domain: Physical Component Score
 Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
PI	Q4W IM	51	47	0.07 (0.670)	1.36 (-0.60, 3.32)	0.175	0.032	0.1153 (0.20392)	(-0.2853, 0.5158)	0.572
	Current ART	54	49	-1.28 (0.748)						
INI	Q4W IM	102	90	1.24 (0.485)	1.71 (0.30, 3.12)	0.017	0.032	0.2027 (0.14629)	(-0.0846, 0.4900)	0.166
	Current ART	99	97	-0.47 (0.533)						
NNRTI	Q4W IM	155	135	0.85 (0.395)	-0.05 (-1.21, 1.11)	0.934	0.032	-0.0070 (0.12005)	(-0.2428, 0.2288)	0.954
	Current ART	155	142	0.90 (0.440)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of SF12 scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Overall	Overall	Q4W IM	308	Baseline	303	83.9	16.13	87.5	75.0	100.0	25	100
				Week 24	297	85.0	16.58	87.5	75.0	100.0	19	100
				Week 48	281	86.2	15.54	87.5	75.0	100.0	25	100
				W48 CFB	277	2.3	15.97	0.0	-6.3	12.5	-50	69
		Current ART	308	Baseline	301	85.2	14.04	87.5	75.0	100.0	31	100
				Week 24	297	85.9	15.78	87.5	75.0	100.0	19	100
				Week 48	295	85.3	14.86	87.5	75.0	100.0	25	100
				W48 CFB	289	-0.2	15.92	0.0	-6.3	6.3	-69	56
Age (years)	<35	Q4W IM	80	Baseline	79	87.6	14.51	93.8	75.0	100.0	50	100
				Week 24	75	85.8	15.60	87.5	75.0	100.0	38	100
				Week 48	72	86.9	15.81	90.6	81.3	100.0	38	100
				W48 CFB	71	-0.5	14.73	0.0	-12.5	6.3	-38	50
		Current ART	80	Baseline	79	85.0	14.28	87.5	75.0	100.0	38	100
				Week 24	76	86.9	14.15	90.6	81.3	100.0	50	100
	Week 48			77	84.5	15.50	87.5	75.0	100.0	31	100	
	W48 CFB			77	-0.6	17.18	0.0	-6.3	6.3	-69	50	
	35 - <50	Q4W IM	162	Baseline	158	83.5	15.44	87.5	75.0	100.0	25	100
				Week 24	156	86.3	15.50	90.6	75.0	100.0	38	100
				Week 48	147	87.2	15.00	93.8	81.3	100.0	31	100
				W48 CFB	144	3.5	17.17	0.0	-6.3	12.5	-50	69

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:53

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Age (years)	35 - <50	Current ART	132	Baseline	129	84.7	15.33	87.5	75.0	100.0	31	100
				Week 24	127	84.5	16.61	87.5	75.0	100.0	19	100
				Week 48	126	85.0	14.92	87.5	75.0	100.0	25	100
				W48 CFB	123	-0.1	16.55	0.0	-6.3	6.3	-63	56
	>=50	Q4W IM	66	Baseline	66	80.3	18.71	87.5	68.8	100.0	38	100
				Week 24	66	81.1	19.55	84.4	68.8	100.0	19	100
				Week 48	62	82.9	16.28	81.3	75.0	100.0	25	100
				W48 CFB	62	2.9	14.17	0.0	-6.3	12.5	-31	38
		Current ART	96	Baseline	93	86.0	11.92	87.5	75.0	93.8	50	100
				Week 24	94	87.0	15.91	93.8	81.3	100.0	19	100
				Week 48	92	86.2	14.34	87.5	81.3	100.0	38	100
				W48 CFB	89	0.1	13.96	0.0	-6.3	6.3	-56	38
Sex at birth	Female	Q4W IM	99	Baseline	96	83.8	17.70	87.5	75.0	100.0	25	100
				Week 24	97	87.8	14.78	93.8	81.3	100.0	38	100
				Week 48	90	89.0	14.34	93.8	81.3	100.0	31	100
				W48 CFB	88	4.9	15.91	0.0	0.0	12.5	-38	69
		Current ART	104	Baseline	100	85.4	13.71	87.5	75.0	100.0	38	100
				Week 24	99	86.6	15.37	93.8	75.0	100.0	38	100
				Week 48	99	85.5	15.38	87.5	75.0	100.0	25	100
				W48 CFB	95	-0.1	17.30	0.0	-12.5	12.5	-63	50

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:53

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Sex at birth	Male	Q4W IM	209	Baseline	207	83.9	15.39	87.5	75.0	100.0	38	100
				Week 24	200	83.6	17.26	87.5	75.0	100.0	19	100
				Week 48	191	84.8	15.93	87.5	75.0	100.0	25	100
				W48 CFB	189	1.1	15.89	0.0	-6.3	6.3	-50	50
	Current ART	204	Baseline	201	85.1	14.24	87.5	75.0	100.0	31	100	
			Week 24	198	85.6	16.02	87.5	75.0	100.0	19	100	
			Week 48	196	85.1	14.63	87.5	75.0	100.0	31	100	
			W48 CFB	194	-0.2	15.26	0.0	-6.3	6.3	-69	56	
Race	White	Q4W IM	214	Baseline	213	82.5	16.33	87.5	75.0	100.0	38	100
				Week 24	208	83.6	16.87	87.5	75.0	100.0	19	100
				Week 48	197	84.6	15.62	87.5	75.0	100.0	25	100
				W48 CFB	196	2.3	16.33	0.0	-6.3	12.5	-50	50
	Current ART	207	Baseline	205	84.4	14.57	87.5	75.0	93.8	31	100	
			Week 24	201	85.5	15.78	87.5	75.0	100.0	19	100	
			Week 48	197	85.4	13.79	87.5	75.0	100.0	38	100	
			W48 CFB	196	0.8	15.31	0.0	-6.3	6.3	-38	56	
Non-White	Q4W IM	94	Baseline	90	87.0	15.26	90.6	75.0	100.0	25	100	
			Week 24	89	88.3	15.48	93.8	81.3	100.0	38	100	
			Week 48	84	89.7	14.83	100.0	81.3	100.0	38	100	
			W48 CFB	81	2.4	15.17	0.0	0.0	12.5	-38	69	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:53

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: Life Satisfaction Transformed Total Score				Actual								
Subgroup	Category	Treatment	N	Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Race	Non-White	Current ART	101	Baseline	96	87.0	12.72	87.5	75.0	100.0	44	100
				Week 24	96	86.7	15.84	93.8	75.0	100.0	31	100
				Week 48	98	84.9	16.88	87.5	75.0	100.0	25	100
				W48 CFB	93	-2.2	17.06	0.0	-12.5	6.3	-69	31
Region	North America	Q4W IM	93	Baseline	91	87.6	14.92	93.8	81.3	100.0	50	100
				Week 24	90	85.8	17.17	93.8	75.0	100.0	19	100
				Week 48	88	86.1	16.92	87.5	78.1	100.0	25	100
				W48 CFB	87	-1.4	13.37	0.0	-12.5	0.0	-38	44
		Current ART	107	Baseline	106	85.9	12.41	87.5	75.0	100.0	44	100
				Week 24	105	84.3	18.51	87.5	75.0	100.0	19	100
				Week 48	101	85.4	15.39	87.5	75.0	100.0	38	100
				W48 CFB	101	-1.1	13.42	0.0	-6.3	6.3	-56	31
	Europe	Q4W IM	145	Baseline	142	82.1	16.32	87.5	75.0	93.8	25	100
				Week 24	140	84.0	15.73	87.5	75.0	100.0	38	100
				Week 48	131	85.4	14.33	87.5	75.0	100.0	31	100
				W48 CFB	128	3.5	17.28	0.0	-6.3	12.5	-50	69
	Current ART	146	Baseline	143	85.1	15.27	87.5	75.0	100.0	31	100	
			Week 24	140	86.3	13.86	87.5	75.0	100.0	31	100	
			Week 48	139	84.4	15.28	87.5	75.0	100.0	25	100	
			W48 CFB	136	-0.6	18.03	0.0	-6.3	6.3	-69	56	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:53

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Region	Rest of World	Q4W IM	70	Baseline	70	82.7	16.66	87.5	68.8	100.0	38	100
				Week 24	67	85.8	17.63	93.8	75.0	100.0	38	100
				Week 48	62	88.0	16.06	96.9	75.0	100.0	44	100
				W48 CFB	62	5.1	15.78	3.1	0.0	12.5	-38	50
	Current ART	55	Baseline	52	84.1	13.81	84.4	75.0	96.9	44	100	
			Week 24	52	88.1	14.61	93.8	81.3	100.0	38	100	
			Week 48	55	87.2	12.70	87.5	75.0	100.0	56	100	
			W48 CFB	52	2.8	14.40	0.0	-6.3	15.6	-31	31	
	Baseline third PI agent class	Q4W IM	51	Baseline	51	83.9	15.90	87.5	75.0	100.0	38	100
				Week 24	51	82.1	17.05	81.3	68.8	100.0	38	100
				Week 48	47	87.0	15.63	93.8	75.0	100.0	44	100
				W48 CFB	47	2.8	15.33	0.0	0.0	12.5	-50	38
Current ART		54	Baseline	52	83.9	12.58	87.5	75.0	93.8	38	100	
			Week 24	52	85.5	12.42	87.5	75.0	96.9	56	100	
			Week 48	52	83.5	13.56	87.5	75.0	93.8	44	100	
			W48 CFB	50	-0.8	16.30	0.0	-6.3	6.3	-56	50	
INI	Q4W IM	102	Baseline	100	82.9	17.08	87.5	68.8	100.0	44	100	
			Week 24	99	83.5	17.39	87.5	68.8	100.0	19	100	
			Week 48	94	84.6	16.26	87.5	75.0	100.0	25	100	
			W48 CFB	92	1.0	14.24	0.0	-6.3	6.3	-25	44	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:53

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Baseline third INI agent class	Current ART	99	Baseline	98	85.3	13.41	87.5	75.0	100.0	50	100	
			Week 24	97	85.0	17.99	87.5	75.0	100.0	19	100	
			Week 48	97	85.4	13.97	87.5	75.0	100.0	50	100	
			W48 CFB	97	0.0	14.57	0.0	-6.3	6.3	-31	50	
	NNRTI	Q4W IM	155	Baseline	152	84.5	15.63	87.5	75.0	100.0	25	100
				Week 24	147	86.9	15.70	93.8	75.0	100.0	38	100
				Week 48	140	87.0	15.04	93.8	75.0	100.0	31	100
				W48 CFB	138	3.0	17.27	0.0	-6.3	12.5	-44	69
		Current ART	155	Baseline	151	85.6	14.95	87.5	75.0	100.0	31	100
				Week 24	148	86.7	15.35	93.8	75.0	100.0	31	100
				Week 48	146	85.8	15.89	87.5	75.0	100.0	25	100
				W48 CFB	142	-0.1	16.76	0.0	-6.3	12.5	-69	56

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Overall	Overall	Q4W IM	308	Baseline	303	89.1	16.29	95.0	85.0	100.0	0	100
				Week 24	297	93.4	12.33	100.0	90.0	100.0	20	100
				Week 48	281	94.3	12.14	100.0	90.0	100.0	0	100
				W48 CFB	277	4.9	19.36	0.0	0.0	10.0	-100	80
		Current ART	308	Baseline	300	89.2	13.93	95.0	85.0	100.0	25	100
				Week 24	297	88.8	14.94	95.0	85.0	100.0	30	100
				Week 48	295	86.9	15.96	90.0	80.0	100.0	20	100
				W48 CFB	288	-2.5	17.42	0.0	-10.0	5.0	-80	75
Age (years)	<35	Q4W IM	80	Baseline	79	89.1	16.21	95.0	85.0	100.0	0	100
				Week 24	75	93.1	12.57	100.0	90.0	100.0	30	100
				Week 48	72	95.3	8.06	100.0	95.0	100.0	65	100
				W48 CFB	71	6.0	15.04	0.0	0.0	10.0	-25	60
		Current ART	80	Baseline	78	86.8	16.14	90.0	80.0	100.0	25	100
				Week 24	76	87.7	14.03	90.0	80.0	100.0	30	100
	Week 48			77	87.9	11.22	90.0	80.0	100.0	55	100	
	W48 CFB			76	1.1	18.88	0.0	-10.0	5.0	-40	75	
	35 - <50	Q4W IM	162	Baseline	158	89.3	15.92	95.0	85.0	100.0	10	100
				Week 24	156	94.3	9.90	100.0	90.0	100.0	35	100
				Week 48	147	93.8	12.81	100.0	90.0	100.0	0	100
				W48 CFB	144	4.1	19.50	0.0	0.0	10.0	-100	80

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:53

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Age (years)	35 - <50	Current ART	132	Baseline	129	89.4	13.79	95.0	80.0	100.0	50	100
				Week 24	127	86.9	16.89	95.0	80.0	100.0	35	100
				Week 48	126	86.2	17.71	95.0	80.0	100.0	30	100
				W48 CFB	123	-3.7	15.61	0.0	-10.0	5.0	-50	30
	>=50	Q4W IM	66	Baseline	66	88.6	17.47	100.0	85.0	100.0	20	100
				Week 24	66	91.5	16.52	100.0	90.0	100.0	20	100
				Week 48	62	94.0	14.38	100.0	95.0	100.0	0	100
				W48 CFB	62	5.6	23.26	0.0	0.0	15.0	-100	70
		Current ART	96	Baseline	93	91.0	11.83	95.0	85.0	100.0	45	100
				Week 24	94	92.2	12.15	95.0	90.0	100.0	40	100
				Week 48	92	87.1	16.91	95.0	80.0	100.0	20	100
				W48 CFB	89	-3.8	18.23	0.0	-10.0	0.0	-80	35
Sex at birth	Female	Q4W IM	99	Baseline	96	90.1	15.22	97.5	85.0	100.0	20	100
				Week 24	97	91.5	15.42	100.0	90.0	100.0	30	100
				Week 48	90	92.9	15.34	100.0	90.0	100.0	0	100
				W48 CFB	88	3.3	21.81	0.0	0.0	10.0	-100	65
		Current ART	104	Baseline	100	85.7	16.52	90.0	75.0	100.0	25	100
				Week 24	99	83.5	19.44	90.0	75.0	100.0	30	100
				Week 48	99	86.1	18.37	95.0	80.0	100.0	20	100
				W48 CFB	95	0.3	20.41	0.0	-10.0	10.0	-80	75

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Sex at birth	Male	Q4W IM	209	Baseline	207	88.6	16.78	95.0	85.0	100.0	0	100
				Week 24	200	94.3	10.44	100.0	90.0	100.0	20	100
				Week 48	191	94.9	10.28	100.0	95.0	100.0	0	100
				W48 CFB	189	5.7	18.11	0.0	0.0	10.0	-100	80
	Current ART	204	Baseline	200	91.0	12.09	95.0	85.0	100.0	30	100	
			Week 24	198	91.4	11.24	95.0	85.0	100.0	40	100	
			Week 48	196	87.3	14.63	90.0	80.0	100.0	20	100	
			W48 CFB	193	-3.8	15.61	0.0	-10.0	0.0	-80	65	
Race	White	Q4W IM	214	Baseline	213	88.7	15.93	95.0	85.0	100.0	10	100
				Week 24	208	93.6	10.93	100.0	90.0	100.0	20	100
				Week 48	197	93.7	12.04	100.0	90.0	100.0	0	100
				W48 CFB	196	4.9	18.83	0.0	0.0	10.0	-100	80
		Current ART	207	Baseline	205	89.5	13.55	95.0	85.0	100.0	25	100
				Week 24	201	88.7	14.79	95.0	85.0	100.0	30	100
				Week 48	197	85.4	16.68	90.0	80.0	100.0	20	100
				W48 CFB	196	-4.2	17.40	0.0	-10.0	0.0	-80	75
	Non-White	Q4W IM	94	Baseline	90	90.1	17.15	100.0	85.0	100.0	0	100
				Week 24	89	92.9	15.17	100.0	95.0	100.0	30	100
				Week 48	84	95.5	12.37	100.0	95.0	100.0	0	100
				W48 CFB	81	5.1	20.70	0.0	0.0	15.0	-100	70

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:53

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Race	Non-White	Current ART	101	Baseline	95	88.7	14.79	95.0	85.0	100.0	35	100
				Week 24	96	88.9	15.33	95.0	85.0	100.0	35	100
				Week 48	98	90.1	13.97	95.0	85.0	100.0	20	100
				W48 CFB	92	1.3	16.93	0.0	-5.0	10.0	-80	65
Region	North America	Q4W IM	93	Baseline	91	91.4	13.21	95.0	90.0	100.0	20	100
				Week 24	90	94.9	12.20	100.0	95.0	100.0	20	100
				Week 48	88	96.5	6.75	100.0	95.0	100.0	70	100
				W48 CFB	87	5.3	13.98	0.0	0.0	5.0	-25	80
		Current ART	107	Baseline	106	90.0	13.31	95.0	85.0	100.0	30	100
				Week 24	105	89.0	15.21	95.0	80.0	100.0	35	100
				Week 48	101	88.6	13.86	95.0	80.0	100.0	35	100
				W48 CFB	101	-1.4	13.89	0.0	-5.0	5.0	-45	65
	Europe	Q4W IM	145	Baseline	142	88.2	16.88	95.0	85.0	100.0	10	100
				Week 24	140	92.8	11.03	100.0	90.0	100.0	45	100
				Week 48	131	92.5	13.76	100.0	90.0	100.0	0	100
				W48 CFB	128	4.0	20.93	0.0	-5.0	10.0	-100	70
Current ART	146	Baseline	143	88.0	15.19	95.0	80.0	100.0	25	100		
		Week 24	140	87.9	15.39	95.0	80.0	100.0	30	100		
		Week 48	139	83.9	17.66	90.0	75.0	100.0	20	100		
		W48 CFB	136	-4.4	19.57	0.0	-12.5	0.0	-80	75		

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Region	Rest of World	Q4W IM	70	Baseline	70	87.8	18.47	95.0	80.0	100.0	0	100
				Week 24	67	92.7	14.86	100.0	90.0	100.0	30	100
				Week 48	62	94.7	13.93	100.0	95.0	100.0	0	100
				W48 CFB	62	6.4	22.44	0.0	0.0	20.0	-100	70
	Current ART	55	Baseline	51	90.9	11.21	95.0	85.0	100.0	60	100	
			Week 24	52	90.7	13.14	95.0	85.0	100.0	40	100	
			Week 48	55	91.5	13.54	95.0	85.0	100.0	20	100	
			W48 CFB	51	0.6	17.28	0.0	-5.0	10.0	-80	35	
	Baseline third PI agent class	Q4W IM	51	Baseline	51	84.7	16.95	90.0	75.0	100.0	30	100
				Week 24	51	92.5	11.93	100.0	85.0	100.0	40	100
				Week 48	47	93.4	10.17	100.0	90.0	100.0	65	100
				W48 CFB	47	9.7	21.27	5.0	0.0	20.0	-35	70
Current ART		54	Baseline	52	86.2	15.39	90.0	77.5	100.0	50	100	
			Week 24	52	87.7	17.56	95.0	85.0	100.0	30	100	
			Week 48	52	83.0	19.18	90.0	72.5	100.0	30	100	
			W48 CFB	50	-3.0	18.57	0.0	-15.0	10.0	-45	30	
INI	Q4W IM	102	Baseline	100	92.5	10.48	95.0	90.0	100.0	50	100	
			Week 24	99	93.6	12.39	100.0	90.0	100.0	20	100	
			Week 48	94	94.2	12.41	100.0	90.0	100.0	0	100	
			W48 CFB	92	1.7	14.21	0.0	0.0	5.0	-100	45	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:53

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Baseline third INI agent class	Current ART	99	Baseline	98	90.1	13.35	95.0	85.0	100.0	30	100	
			Week 24	97	89.9	13.64	95.0	85.0	100.0	40	100	
			Week 48	97	88.5	13.70	90.0	80.0	100.0	30	100	
			W48 CFB	97	-1.5	15.25	0.0	-10.0	5.0	-50	65	
	NNRTI	Q4W IM	155	Baseline	152	88.4	18.68	95.0	85.0	100.0	0	100
				Week 24	147	93.6	12.50	100.0	90.0	100.0	30	100
				Week 48	140	94.6	12.63	100.0	95.0	100.0	0	100
				W48 CFB	138	5.5	21.30	0.0	0.0	10.0	-100	80
		Current ART	155	Baseline	150	89.7	13.72	95.0	85.0	100.0	25	100
				Week 24	148	88.4	14.82	95.0	80.0	100.0	35	100
				Week 48	146	87.3	15.99	95.0	80.0	100.0	20	100
				W48 CFB	141	-2.9	18.46	0.0	-10.0	0.0	-80	75

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Subgroup	Category	Treatment	N	Score Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Overall	Overall	Q4W IM	308	Baseline	302	64.1	29.99	70.0	40.0	90.0	0	100	
				Week 24	297	70.8	28.31	80.0	50.0	95.0	0	100	
				Week 48	281	67.9	28.44	75.0	50.0	90.0	0	100	
				W48 CFB	276	3.5	28.66	0.0	-10.0	15.0	-85	100	
			Current ART	308	Baseline	300	58.7	31.08	60.0	35.0	85.0	0	100
				Week 24	297	63.5	29.90	70.0	45.0	90.0	0	100	
				Week 48	295	62.9	31.46	70.0	40.0	90.0	0	100	
				W48 CFB	288	4.0	30.08	0.0	-10.0	15.0	-95	100	
Age (years)	<35	Q4W IM	80	Baseline	79	64.9	28.37	75.0	40.0	90.0	0	100	
				Week 24	75	69.9	28.83	80.0	50.0	95.0	0	100	
				Week 48	72	68.5	28.61	75.0	52.5	90.0	0	100	
				W48 CFB	71	2.0	28.96	0.0	-15.0	15.0	-85	75	
			Current ART	80	Baseline	78	56.0	31.20	60.0	30.0	80.0	0	100
				Week 24	76	61.7	32.90	70.0	35.0	90.0	0	100	
		Week 48		77	61.0	33.95	75.0	35.0	90.0	0	100		
		W48 CFB		76	4.3	28.83	0.0	-10.0	15.0	-80	90		
		35 - <50	Q4W IM	162	Baseline	158	63.5	30.23	70.0	40.0	90.0	0	100
				Week 24	156	72.1	28.77	85.0	55.0	95.0	0	100	
				Week 48	147	67.0	28.51	75.0	50.0	90.0	0	100	
				W48 CFB	144	4.2	30.42	0.0	-10.0	15.0	-75	100	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: Disclosure Worries Transformed Total Score				Actual								
Subgroup	Category	Treatment	N	Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Age (years)	35 - <50	Current ART	132	Baseline	130	57.9	29.11	60.0	40.0	80.0	0	100
				Week 24	127	61.0	28.96	60.0	45.0	85.0	0	100
				Week 48	126	63.0	29.97	65.0	40.0	95.0	0	100
				W48 CFB	124	4.9	32.38	0.0	-14.4	15.0	-95	100
	>=50	Q4W IM	66	Baseline	65	64.5	31.71	70.0	40.0	90.0	0	100
				Week 24	66	68.9	26.83	75.0	50.0	95.0	0	100
				Week 48	62	69.1	28.49	77.5	55.0	95.0	0	100
				W48 CFB	61	3.7	23.99	0.0	-10.0	15.0	-40	75
		Current ART	96	Baseline	92	62.1	33.62	70.0	35.0	90.0	0	100
				Week 24	94	68.4	28.31	77.5	50.0	90.0	0	100
				Week 48	92	64.2	31.58	72.5	40.0	90.0	0	100
				W48 CFB	88	2.4	27.96	0.0	-10.0	17.5	-70	80
Sex at birth	Female	Q4W IM	99	Baseline	96	61.5	30.76	65.0	35.0	90.0	0	100
				Week 24	97	70.1	28.92	80.0	50.0	95.0	0	100
				Week 48	90	65.6	31.36	75.0	40.0	90.0	0	100
				W48 CFB	88	4.7	30.37	0.0	-10.0	20.0	-60	95
		Current ART	104	Baseline	101	52.1	32.31	55.0	25.0	80.0	0	100
				Week 24	99	56.4	29.73	60.0	35.0	80.0	0	100
				Week 48	99	57.7	32.12	60.0	25.0	85.0	0	100
				W48 CFB	96	5.8	32.95	0.0	-15.0	20.0	-70	100

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:53

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Subgroup	Category	Treatment	N	Score Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Sex at birth	Male	Q4W IM	209	Baseline	206	65.3	29.63	75.0	45.0	90.0	0	100
				Week 24	200	71.2	28.07	80.0	52.5	95.0	0	100
				Week 48	191	69.0	26.98	75.0	50.0	90.0	0	100
				W48 CFB	188	3.0	27.89	0.0	-10.0	15.0	-85	100
	Current ART	204	Baseline	199	62.0	29.98	70.0	35.0	90.0	0	100	
			Week 24	198	67.1	29.41	75.0	50.0	90.0	0	100	
			Week 48	196	65.5	30.88	75.0	40.0	95.0	0	100	
			W48 CFB	192	3.1	28.58	0.0	-10.0	15.0	-95	85	
Race	White	Q4W IM	214	Baseline	212	64.9	28.33	70.0	45.0	90.0	0	100
				Week 24	208	70.4	27.02	80.0	52.5	90.0	0	100
				Week 48	197	66.2	28.30	75.0	50.0	90.0	0	100
				W48 CFB	195	0.8	24.97	0.0	-10.0	15.0	-75	75
	Current ART	207	Baseline	205	60.3	30.11	60.0	35.0	85.0	0	100	
			Week 24	201	64.6	28.60	70.0	45.0	90.0	0	100	
			Week 48	197	62.7	31.16	70.0	40.0	90.0	0	100	
			W48 CFB	196	2.2	29.59	0.0	-15.0	15.0	-95	90	
Non-White	Q4W IM	94	Baseline	90	62.2	33.69	75.0	40.0	90.0	0	100	
			Week 24	89	71.8	31.25	85.0	50.0	100.0	0	100	
			Week 48	84	71.7	28.58	80.0	55.0	100.0	0	100	
			W48 CFB	81	10.1	35.35	0.0	-10.0	30.0	-85	100	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:53

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: Disclosure Worries Transformed Total Score				Actual Relative								
Subgroup	Category	Treatment	N	Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Race	Non-White	Current ART	101	Baseline	95	55.2	32.98	60.0	30.0	80.0	0	100
				Week 24	96	61.3	32.49	70.0	40.0	90.0	0	100
				Week 48	98	63.2	32.22	70.0	40.0	95.0	0	100
				W48 CFB	92	7.9	30.90	5.0	-10.0	20.0	-60	100
Region	North America	Q4W IM	93	Baseline	91	68.8	24.12	75.0	55.0	90.0	0	100
				Week 24	90	75.5	25.07	85.0	60.0	95.0	5	100
				Week 48	88	71.9	25.30	80.0	60.0	90.0	0	100
				W48 CFB	87	2.2	26.65	0.0	-10.0	20.0	-85	65
		Current ART	107	Baseline	106	62.2	29.02	62.5	40.0	90.0	0	100
				Week 24	105	63.4	31.04	70.0	40.0	90.0	0	100
				Week 48	101	62.1	31.36	70.0	40.0	90.0	0	100
				W48 CFB	101	0.2	24.30	0.0	-10.0	10.0	-70	80
	Europe	Q4W IM	145	Baseline	141	61.4	30.49	65.0	40.0	90.0	0	100
				Week 24	140	68.6	28.72	75.0	50.0	90.0	0	100
				Week 48	131	63.8	29.65	70.0	40.0	90.0	0	100
				W48 CFB	127	2.5	26.58	0.0	-10.0	15.0	-50	85
	Current ART	146	Baseline	143	55.5	31.88	60.0	30.0	80.0	0	100	
			Week 24	140	60.6	30.53	65.0	37.5	90.0	0	100	
			Week 48	139	59.7	32.74	65.0	30.0	90.0	0	100	
			W48 CFB	136	3.9	34.17	0.0	-15.0	20.0	-95	100	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Subgroup	Category	Treatment	N	Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Region	Rest of World	Q4W IM	70	Baseline	70	63.3	35.13	75.0	40.0	95.0	0	100
				Week 24	67	69.3	31.08	80.0	40.0	100.0	10	100
				Week 48	62	70.7	29.32	80.0	50.0	100.0	0	100
				W48 CFB	62	7.4	34.96	2.5	-10.0	20.0	-75	100
		Current ART	55	Baseline	51	60.1	32.64	70.0	30.0	90.0	0	100
				Week 24	52	71.5	24.43	80.0	60.0	87.5	0	100
				Week 48	55	72.2	26.73	80.0	60.0	95.0	0	100
				W48 CFB	51	11.6	27.79	5.0	-5.0	25.0	-60	75
	Baseline third PI agent class	Q4W IM	51	Baseline	51	56.3	31.87	65.0	30.0	85.0	0	100
				Week 24	51	64.9	29.61	75.0	40.0	85.0	0	100
				Week 48	47	60.0	27.45	60.0	40.0	85.0	0	100
				W48 CFB	47	3.9	25.44	0.0	-10.0	15.0	-45	75
Current ART		54	Baseline	52	57.5	32.68	60.0	32.5	87.5	0	100	
			Week 24	52	58.8	34.01	60.0	27.5	92.5	0	100	
			Week 48	52	56.6	33.69	60.0	25.0	85.0	0	100	
			W48 CFB	50	-0.3	31.81	0.0	-15.0	15.0	-95	80	
INI	Q4W IM	102	Baseline	100	62.6	30.16	70.0	40.0	87.5	0	100	
			Week 24	99	70.0	27.95	80.0	50.0	95.0	5	100	
			Week 48	94	67.2	27.97	75.0	50.0	90.0	0	100	
			W48 CFB	92	3.2	28.24	0.0	-15.0	15.0	-85	85	

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

21OCT2019 06:53

Table 7.04
 Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Baseline third INI agent class	Current ART	99	Baseline	98	55.3	31.46	60.0	30.0	85.0	0	100	
			Week 24	97	65.6	30.80	70.0	45.0	95.0	0	100	
			Week 48	97	63.0	29.89	65.0	40.0	90.0	0	100	
			W48 CFB	97	8.1	28.58	0.0	-10.0	20.0	-60	100	
	NNRTI	Q4W IM	155	Baseline	151	67.7	28.84	75.0	50.0	95.0	0	100
				Week 24	147	73.5	27.93	80.0	60.0	95.0	0	100
				Week 48	140	70.9	28.74	80.0	55.0	97.5	0	100
				W48 CFB	137	3.6	30.13	0.0	-10.0	15.0	-75	100
		Current ART	155	Baseline	150	61.3	30.22	70.0	35.0	85.0	0	100
				Week 24	148	63.8	27.73	70.0	45.0	85.0	0	100
				Week 48	146	65.0	31.59	75.0	40.0	95.0	0	100
				W48 CFB	141	2.7	30.34	0.0	-10.0	15.0	-89	90

Note: Summaries at each visit are for actual values, W48 CFB represents the change from Baseline at Week 48, calculated for subjects with both Baseline and Week 48 data.

PPD

Table 7.05
 Statistical Analysis of Quality of Life (HATQoL)- Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 - Overall - MMRM - ATLAS

Domain: Life Satisfaction Transformed Total Score

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q4W IM	308	277	1.46	0.822	1.36 (-0.93, 3.65)	0.244	0.1001 (0.08402)	(-0.0650, 0.2651)	0.234
Current ART	308	289	0.10	0.824					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, treatment*visit, Maintenance BL (Day 1) Score, sex at birth (female, male), age (<50, >= 50 years), race (white, non-white) and Baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor.

No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.

[2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

PPD

Table 7.05
 Statistical Analysis of Quality of Life (HATQoL)- Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 - Overall - MMRM - ATLAS

Domain: HIV Medication Transformed Total Score

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q4W IM	308	277	4.84	0.740	7.37 (5.06, 9.67)	<.001	0.5394 (0.08563)	(0.3712, 0.7076)	<.001
Current ART	308	288	-2.53	0.911					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, treatment*visit, Maintenance BL (Day 1) Score, sex at birth (female, male), age (<50, >= 50 years), race (white, non-white) and Baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor.

No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.

[2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

PPD

Table 7.05
 Statistical Analysis of Quality of Life (HATQoL)- Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 - Overall - MMRM - ATLAS

Domain: Disclosure Worries Transformed Total Score

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q4W IM	308	276	4.57	1.465	1.94 (-2.27, 6.14)	0.367	0.0757 (0.08415)	(-0.0895, 0.2410)	0.368
Current ART	308	288	2.64	1.554					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, treatment*visit, Maintenance BL (Day 1) Score, sex at birth (female, male), age (<50, >= 50 years), race (white, non-white) and Baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor.

No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.

[2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

PPD

Table 7.06
 Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: Life Satisfaction Transformed Total Score
 Subgroup: Age (years) (< 35 vs. >= 35 - < 50 vs. >= 50)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<35	Q4W IM	80	71	0.92 (1.628)	0.79 (-3.69, 5.27)	0.729	0.147	0.0299 (0.16431)	(-0.2928, 0.3527)	0.855
	Current ART	80	77	0.13 (1.610)						
35 - <50	Q4W IM	162	144	2.66 (1.140)	2.80 (-0.55, 6.16)	0.101	0.147	0.1424 (0.12268)	(-0.0986, 0.3834)	0.246
	Current ART	132	123	-0.14 (1.267)						
>=50	Q4W IM	66	62	-0.45 (1.742)	-0.70 (-5.19, 3.80)	0.761	0.147	-0.0270 (0.16519)	(-0.3515, 0.2975)	0.870
	Current ART	96	89	0.25 (1.484)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06

Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: Life Satisfaction Transformed Total Score
 Subgroup: Sex at Birth (Female vs. Male)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
Female	Q4W IM	99	88	3.66 (1.478)	3.36 (-0.65, 7.37)	0.100	0.180	0.1418 (0.14781)	(-0.1486, 0.4321)	0.338
	Current ART	104	95	0.30 (1.456)						
Male	Q4W IM	209	189	0.41 (1.008)	0.38 (-2.40, 3.17)	0.787	0.180	0.0233 (0.10206)	(-0.1772, 0.2238)	0.820
	Current ART	204	194	0.02 (1.008)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06

Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: Life Satisfaction Transformed Total Score
 Subgroup: Race (White vs. Non-White)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
White	Q4W IM	214	196	1.06 (0.985)	0.29 (-2.46, 3.03)	0.838	0.203	0.0176 (0.10088)	(-0.1806, 0.2157)	0.862
	Current ART	207	196	0.77 (1.000)						
Non-White	Q4W IM	94	81	2.42 (1.538)	3.71 (-0.41, 7.83)	0.077	0.203	0.1533 (0.15184)	(-0.1450, 0.4516)	0.313
	Current ART	101	93	-1.30 (1.468)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06
 Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: Life Satisfaction Transformed Total Score
 Subgroup: Region (North America vs. Europe vs. Rest of World)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
North America	Q4W IM	93	87	0.09 (1.525)	0.34 (-3.65, 4.34)	0.866	0.908	0.0147 (0.14606)	(-0.2723, 0.3016)	0.920
	Current ART	107	101	-0.26 (1.436)						
Europe	Q4W IM	145	128	1.43 (1.264)	1.87 (-1.48, 5.21)	0.273	0.908	0.0943 (0.12301)	(-0.1474, 0.3359)	0.444
	Current ART	146	136	-0.43 (1.248)						
Rest of World	Q4W IM	70	62	3.42 (1.823)	1.10 (-4.04, 6.25)	0.673	0.908	0.0367 (0.18778)	(-0.3322, 0.4056)	0.845
	Current ART	55	52	2.31 (2.092)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06
 Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: Life Satisfaction Transformed Total Score
 Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
PI	Q4W IM	51	47	1.06 (1.994)	2.11 (-3.39, 7.62)	0.451	0.745	0.0649 (0.20289)	(-0.3337, 0.4634)	0.749
	Current ART	54	50	-1.06 (1.992)						
INI	Q4W IM	102	92	0.63 (1.432)	0.29 (-3.67, 4.24)	0.887	0.745	0.0122 (0.14533)	(-0.2733, 0.2977)	0.933
	Current ART	99	97	0.35 (1.432)						
NNRTI	Q4W IM	155	138	2.19 (1.167)	1.86 (-1.40, 5.12)	0.264	0.745	0.0961 (0.11941)	(-0.1385, 0.3306)	0.421
	Current ART	155	142	0.33 (1.180)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06
 Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: HIV Medication Transformed Total Score
 Subgroup: Age (years) (< 35 vs. >= 35 - < 50 vs. >= 50)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<35	Q4W IM	80	71	5.76 (1.465)	7.40 (2.88, 11.92)	0.001	0.150	0.2774 (0.16504)	(-0.0468, 0.6016)	0.093
	Current ART	80	76	-1.64 (1.785)						
35 - <50	Q4W IM	162	144	4.49 (1.028)	7.70 (4.28, 11.11)	<.001	0.150	0.3913 (0.12320)	(0.1493, 0.6334)	0.002
	Current ART	132	123	-3.21 (1.398)						
>=50	Q4W IM	66	62	4.51 (1.566)	6.84 (2.39, 11.29)	0.003	0.150	0.2607 (0.16539)	(-0.0641, 0.5856)	0.116
	Current ART	96	89	-2.33 (1.642)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06

Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: HIV Medication Transformed Total Score
 Subgroup: Sex at Birth (Female vs. Male)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
Female	Q4W IM	99	88	2.84 (1.330)	6.19 (2.14, 10.23)	0.003	0.500	0.2580 (0.14796)	(-0.0326, 0.5487)	0.082
	Current ART	104	95	-3.35 (1.602)						
Male	Q4W IM	209	189	5.80 (0.905)	7.96 (5.15, 10.77)	<.001	0.500	0.4791 (0.10323)	(0.2763, 0.6819)	<.001
	Current ART	204	193	-2.16 (1.115)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06

Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: HIV Medication Transformed Total Score
 Subgroup: Race (White vs. Non-White)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
White	Q4W IM	214	196	4.09 (0.885)	8.40 (5.63, 11.17)	<.001	0.431	0.5132 (0.10208)	(0.3127, 0.7137)	<.001
	Current ART	207	196	-4.31 (1.101)						
Non-White	Q4W IM	94	81	6.56 (1.384)	5.21 (1.07, 9.35)	0.014	0.431	0.2117 (0.15229)	(-0.0875, 0.5108)	0.165
	Current ART	101	92	1.36 (1.613)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06
 Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: HIV Medication Transformed Total Score
 Subgroup: Region (North America vs. Europe vs. Rest of World)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
North America	Q4W IM	93	87	6.91 (1.347)	7.92 (3.96, 11.88)	<.001	0.189	0.3363 (0.14642)	(0.0486, 0.6239)	0.022
	Current ART	107	101	-1.01 (1.557)						
Europe	Q4W IM	145	128	3.28 (1.126)	8.56 (5.22, 11.91)	<.001	0.189	0.4329 (0.12368)	(0.1899, 0.6758)	<.001
	Current ART	146	136	-5.28 (1.347)						
Rest of World	Q4W IM	70	62	5.10 (1.621)	3.12 (-2.11, 8.35)	0.241	0.189	0.1039 (0.18879)	(-0.2670, 0.4748)	0.582
	Current ART	55	51	1.98 (2.241)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06
 Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: HIV Medication Transformed Total Score
 Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
PI	Q4W IM	51	47	5.55 (1.812)	10.89 (5.34, 16.44)	<.001	0.364	0.3323 (0.20314)	(-0.0668, 0.7313)	0.102
	Current ART	54	50	-5.34 (2.190)						
INI	Q4W IM	102	92	4.02 (1.297)	5.40 (1.42, 9.38)	0.008	0.364	0.2297 (0.14550)	(-0.0561, 0.5156)	0.115
	Current ART	99	97	-1.38 (1.571)						
NNRTI	Q4W IM	155	138	5.15 (1.052)	7.47 (4.18, 10.76)	<.001	0.364	0.3847 (0.12015)	(0.1487, 0.6207)	0.001
	Current ART	155	141	-2.32 (1.303)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06

Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: Disclosure Worries Transformed Total Score
 Subgroup: Age (years) (< 35 vs. >= 35 - < 50 vs. >= 50)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
<35	Q4W IM	80	71	3.75 (2.903)	2.47 (-5.79, 10.73)	0.557	0.654	0.0496 (0.16484)	(-0.2742, 0.3734)	0.764
	Current ART	80	76	1.28 (3.053)						
35 - <50	Q4W IM	162	144	4.53 (2.034)	0.98 (-5.17, 7.13)	0.755	0.654	0.0265 (0.12235)	(-0.2138, 0.2669)	0.828
	Current ART	132	124	3.55 (2.376)						
>=50	Q4W IM	66	61	5.42 (3.124)	2.77 (-5.46, 11.01)	0.509	0.654	0.0571 (0.16639)	(-0.2697, 0.3840)	0.731
	Current ART	96	88	2.65 (2.807)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06
 Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: Disclosure Worries Transformed Total Score
 Subgroup: Sex at Birth (Female vs. Male)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
Female	Q4W IM	99	88	3.52 (2.628)	2.29 (-5.06, 9.64)	0.541	0.292	0.0515 (0.14739)	(-0.2380, 0.3410)	0.727
	Current ART	104	96	1.22 (2.743)						
Male	Q4W IM	209	188	5.08 (1.800)	1.75 (-3.37, 6.88)	0.502	0.292	0.0566 (0.10248)	(-0.1447, 0.2579)	0.581
	Current ART	204	192	3.33 (1.912)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06

Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: Disclosure Worries Transformed Total Score
 Subgroup: Race (White vs. Non-White)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
White	Q4W IM	214	195	2.07 (1.748)	0.51 (-4.53, 5.55)	0.842	0.184	0.0167 (0.10101)	(-0.1817, 0.2151)	0.869
	Current ART	207	196	1.56 (1.888)						
Non-White	Q4W IM	94	81	10.48 (2.720)	5.43 (-2.14, 13.00)	0.159	0.184	0.1188 (0.15220)	(-0.1802, 0.4177)	0.436
	Current ART	101	92	5.05 (2.786)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06

Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: Disclosure Worries Transformed Total Score
 Subgroup: Region (North America vs. Europe vs. Rest of World)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
North America	Q4W IM	93	87	4.72 (2.717)	5.69 (-1.60, 12.98)	0.126	0.144	0.1296 (0.14613)	(-0.1574, 0.4166)	0.376
	Current ART	107	101	-0.97 (2.672)						
Europe	Q4W IM	145	127	2.98 (2.256)	0.51 (-5.60, 6.62)	0.870	0.144	0.0138 (0.12323)	(-0.2282, 0.2559)	0.911
	Current ART	146	136	2.47 (2.331)						
Rest of World	Q4W IM	70	62	7.60 (3.237)	-2.93 (-12.41, 6.54)	0.543	0.144	-0.0520 (0.18879)	(-0.4229, 0.3188)	0.783
	Current ART	55	51	10.53 (3.901)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.06
 Statistical Analysis of Quality of Life (HATQoL) Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 by Subgroup - MMRM - ATLAS

Domain: Disclosure Worries Transformed Total Score
 Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								(S.E)	95% CI	P-value
PI	Q4W IM	51	47	1.45 (3.552)	3.19 (-6.90, 13.28)	0.535	0.288	0.0523 (0.20290)	(-0.3462, 0.4509)	0.797
	Current ART	54	50	-1.74 (3.748)						
INI	Q4W IM	102	92	3.67 (2.548)	-1.25 (-8.51, 6.00)	0.735	0.288	-0.0286 (0.14534)	(-0.3141, 0.2569)	0.844
	Current ART	99	97	4.92 (2.704)						
NNRTI	Q4W IM	155	137	6.29 (2.094)	3.64 (-2.36, 9.63)	0.234	0.288	0.1001 (0.11984)	(-0.1353, 0.3355)	0.404
	Current ART	155	141	2.65 (2.226)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.07
 Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Overall	Overall	Q4W IM	308	Baseline	302	55.25	9.136	57.00	50.00	62.00	11.0	66.0
				Week 4B	301	59.28	7.298	61.00	56.00	65.00	19.0	66.0
				Week 24	290	61.80	6.648	64.00	60.00	66.00	11.0	66.0
				Week 44	282	61.80	5.307	64.00	59.00	66.00	41.0	66.0
		W44 CFB	277	6.46	10.283	5.00	0.00	12.00	-23.0	55.0		
		Current ART	308	Baseline	298	55.40	8.682	57.00	50.00	63.00	26.0	66.0
				Week 24	293	56.27	9.568	58.00	52.00	65.00	8.0	66.0
				Week 44	294	55.95	9.885	58.00	51.00	65.00	7.0	66.0
W44 CFB	285			0.38	9.910	0.00	-5.00	7.00	-29.0	31.0		
Age (years)	<35	Q4W IM	80	Baseline	79	55.34	8.232	56.00	50.00	61.00	28.0	66.0
				Week 4B	78	59.01	8.189	61.00	55.00	65.00	19.0	66.0
				Week 24	73	61.82	7.464	64.00	61.00	66.00	11.0	66.0
				Week 44	71	62.20	5.073	64.00	60.00	66.00	41.0	66.0
		W44 CFB	70	6.67	9.630	6.00	2.00	12.00	-17.0	38.0		
		Current ART	80	Baseline	77	52.92	8.209	54.00	48.00	59.00	26.0	66.0
				Week 24	76	54.55	9.379	56.50	50.00	61.50	28.0	66.0
				Week 44	78	54.44	9.719	55.00	50.00	63.00	21.0	66.0
	W44 CFB			76	1.25	10.344	0.50	-5.00	8.00	-27.0	27.0	
	35 - <50	Q4W IM	162	Baseline	157	55.20	9.662	57.00	50.00	63.00	11.0	66.0
				Week 4B	159	59.79	6.689	61.00	57.00	65.00	22.0	66.0
				Week 24	153	62.22	5.674	65.00	61.00	66.00	33.0	66.0
Week 44				149	61.48	5.356	63.00	59.00	66.00	42.0	66.0	
W44 CFB	145	6.10	10.947	5.00	0.00	12.00	-16.0	55.0				

Note: Summaries at each visit are for actual values, W44 CFB represents the change from Baseline at Week 44, calculated for subjects with both Baseline and Week 44 data.

PPD

21OCT2019 06:52

Table 7.07
 Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Age (years)	35 - <50	Current ART	132	Baseline	128	54.82	8.970	56.00	49.00	62.00	30.0	66.0	
				Week 24	126	55.02	10.832	57.00	49.00	65.00	8.0	66.0	
				Week 44	126	54.79	10.988	56.00	48.00	65.00	7.0	66.0	
				W44 CFB	122	-0.18	11.125	0.00	-6.00	7.00	-29.0	31.0	
		>=50	Q4W IM	66	Baseline	66	55.24	9.004	57.00	50.00	63.00	27.0	66.0
					Week 4B	64	58.34	7.601	60.50	55.00	64.50	37.0	66.0
	Week 24				64	60.77	7.737	64.50	58.50	66.00	25.0	66.0	
	Week 44				62	62.13	5.482	64.00	60.00	66.00	41.0	66.0	
	W44 CFB		62	7.05	9.482	5.50	0.00	12.00	-23.0	33.0			
	Current ART		96	Baseline	93	58.25	7.921	60.00	54.00	65.00	33.0	66.0	
		Week 24		91	59.45	6.771	61.00	55.00	66.00	38.0	66.0		
	Sex at birth	Female	Q4W IM	99	Baseline	96	55.54	9.461	56.69	50.00	64.00	28.0	66.0
Week 4B					97	59.38	7.523	61.00	57.00	65.00	19.0	66.0	
Week 24					94	63.04	6.524	65.00	62.00	66.00	11.0	66.0	
Week 44					92	62.71	4.293	64.00	61.00	66.00	41.0	66.0	
W44 CFB			90	7.48	11.208	5.00	0.00	14.00	-23.0	38.0			
Current ART			104	Baseline	100	53.29	9.608	54.00	47.00	61.00	31.0	66.0	
		Week 24		98	53.58	10.564	55.00	48.00	63.00	8.0	66.0		
					Week 44	99	54.91	10.804	57.00	49.00	63.00	7.0	66.0
					W44 CFB	95	1.33	11.714	1.00	-6.00	10.00	-27.0	31.0

Note: Summaries at each visit are for actual values, W44 CFB represents the change from Baseline at Week 44, calculated for subjects with both Baseline and Week 44 data.

PPD

21OCT2019 06:52

Table 7.07
 Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Sex at birth	Male	Q4W IM	209	Baseline	206	55.11	9.000	57.00	50.00	61.00	11.0	66.0
				Week 4B	204	59.23	7.207	61.00	56.00	65.00	22.0	66.0
				Week 24	196	61.20	6.640	64.00	59.00	66.00	25.0	66.0
				Week 44	190	61.36	5.692	64.00	59.00	66.00	41.0	66.0
	W44 CFB	187	5.97	9.801	5.00	0.00	11.00	-17.0	55.0			
	Current ART	204	Baseline	198	56.46	7.991	57.00	53.00	63.00	26.0	66.0	
			Week 24	195	57.63	8.746	59.00	53.00	66.00	11.0	66.0	
			Week 44	195	56.48	9.368	58.00	51.00	65.00	21.0	66.0	
W44 CFB			190	-0.10	8.868	0.00	-5.00	6.00	-29.0	23.0		
Race	White	Q4W IM	214	Baseline	212	54.90	8.534	56.00	50.00	61.00	11.0	66.0
				Week 4B	209	59.17	7.171	61.00	56.00	64.00	22.0	66.0
				Week 24	204	61.55	6.022	64.00	59.00	66.00	25.0	66.0
				Week 44	196	61.29	5.646	63.00	59.00	66.00	41.0	66.0
		W44 CFB	194	6.26	9.977	5.00	0.00	12.00	-23.0	55.0		
		Current ART	207	Baseline	204	55.96	8.299	57.60	52.00	62.00	26.0	66.0
				Week 24	197	56.65	9.075	58.00	52.00	64.00	8.0	66.0
				Week 44	197	55.28	10.285	57.00	50.00	64.00	7.0	66.0
	W44 CFB			195	-0.85	9.685	0.00	-6.00	5.00	-29.0	31.0	
	Non-White	Q4W IM	94	Baseline	90	56.06	10.423	58.00	52.00	65.00	27.0	66.0
				Week 4B	92	59.53	7.612	62.00	55.00	66.00	19.0	66.0
				Week 24	86	62.38	7.946	65.00	62.00	66.00	11.0	66.0
Week 44				86	62.98	4.237	65.00	61.00	66.00	46.0	66.0	
W44 CFB	83	6.92	11.015	5.00	0.00	12.00	-15.0	38.0				

Note: Summaries at each visit are for actual values, W44 CFB represents the change from Baseline at Week 44, calculated for subjects with both Baseline and Week 44 data.

PPD

21OCT2019 06:52

Table 7.07
 Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Race	Non-White	Current ART	101	Baseline	94	54.19	9.393	55.00	48.00	63.00	30.0	66.0
				Week 24	96	55.50	10.515	57.00	50.00	65.00	11.0	66.0
				Week 44	97	57.32	8.912	60.00	53.00	65.00	29.0	66.0
				W44 CFB	90	3.03	9.926	2.00	-2.00	9.00	-27.0	27.0
Region	North America	Q4W IM	93	Baseline	91	57.37	9.270	59.00	53.00	65.00	11.0	66.0
				Week 4B	91	59.45	8.803	63.00	56.00	66.00	19.0	66.0
				Week 24	89	62.61	6.946	66.00	62.00	66.00	25.0	66.0
				Week 44	86	62.44	5.455	65.00	61.00	66.00	41.0	66.0
		W44 CFB	85	4.62	10.547	2.00	0.00	10.00	-17.0	55.0		
		Current ART	107	Baseline	105	57.15	7.187	58.00	52.00	63.00	39.0	66.0
				Week 24	102	57.95	9.080	60.50	53.00	66.00	29.0	66.0
				Week 44	101	58.14	8.103	61.00	53.00	65.00	32.0	66.0
	W44 CFB			100	0.89	7.712	0.00	-2.00	6.00	-23.0	17.0	
	Europe	Q4W IM	145	Baseline	142	54.80	8.189	56.00	50.00	61.00	22.0	66.0
				Week 4B	141	59.82	5.974	61.00	57.00	64.00	39.0	66.0
				Week 24	137	61.47	4.884	63.00	59.00	65.00	42.0	66.0
Week 44				133	60.81	5.567	62.00	58.00	66.00	41.0	66.0	
W44 CFB		130	6.15	9.613	6.00	1.00	12.00	-23.0	34.0			
Current ART		146	Baseline	144	55.19	8.961	57.00	49.50	62.50	26.0	66.0	
			Week 24	139	55.27	9.255	57.00	50.00	62.00	8.0	66.0	
			Week 44	142	53.88	10.683	55.50	48.00	62.00	7.0	66.0	
	W44 CFB		140	-1.27	10.372	-0.50	-8.00	5.00	-29.0	31.0		

Note: Summaries at each visit are for actual values, W44 CFB represents the change from Baseline at Week 44, calculated for subjects with both Baseline and Week 44 data.

PPD

21OCT2019 06:52

Table 7.07
 Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Region	Rest of World	Q4W IM	70	Baseline	69	53.38	10.327	56.00	46.00	61.00	27.0	66.0	
				Week 4B	69	57.96	7.516	60.00	55.00	64.00	22.0	66.0	
				Week 24	64	61.36	9.082	65.00	61.00	66.00	11.0	66.0	
				Week 44	63	63.02	4.086	65.00	61.00	66.00	49.0	66.0	
			W44 CFB	62	9.63	10.710	7.00	2.00	16.00	-15.0	33.0		
		Current ART	55	Baseline	49	52.27	9.918	55.00	45.00	59.00	30.0	66.0	
	Week 24			52	55.65	10.972	57.00	50.50	65.00	11.0	66.0		
	Week 44			51	57.39	9.770	60.00	54.00	65.00	29.0	66.0		
	W44 CFB			45	4.38	11.604	4.00	-3.00	12.00	-27.0	27.0		
	Baseline third PI agent class	Q4W IM	51	Baseline	51	51.75	10.185	55.00	46.00	60.00	27.0	66.0	
				Week 4B	51	59.73	7.484	61.00	58.00	65.00	19.0	66.0	
				Week 24	50	61.50	6.569	64.00	59.00	66.00	33.0	66.0	
Week 44				47	61.26	4.993	64.00	58.00	65.00	48.0	66.0		
			W44 CFB	47	9.74	11.394	9.00	2.00	17.00	-16.0	38.0		
		Current ART	54	Baseline	52	50.51	9.909	52.00	45.50	58.50	26.0	66.0	
Week 24				52	51.17	11.059	52.00	47.00	59.50	8.0	66.0		
Week 44				52	51.92	12.942	54.50	44.00	61.50	7.0	66.0		
W44 CFB				50	1.17	12.260	1.00	-6.00	7.00	-28.0	31.0		
		INI	Q4W IM	102	Baseline	100	56.93	6.971	58.00	52.50	63.00	31.0	66.0
Week 4B					101	58.91	7.399	61.00	55.00	66.00	37.0	66.0	
Week 24					97	61.39	6.955	64.00	60.00	66.00	25.0	66.0	
Week 44	94				61.74	6.128	64.00	60.00	66.00	41.0	66.0		
		W44 CFB	92	4.26	8.781	4.00	0.00	10.00	-23.0	32.0			

Note: Summaries at each visit are for actual values, W44 CFB represents the change from Baseline at Week 44, calculated for subjects with both Baseline and Week 44 data.

PPD

21OCT2019 06:52

Table 7.07
 Summary of HIVTSQs - Total Treatment Satisfaction Score by Visit (Maintenance Phase) - Overall
 and by Subgroup - ATLAS

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Baseline third agent class	INI	Current ART	99	Baseline	97	56.39	7.774	57.00	52.00	63.00	33.0	66.0
				Week 24	96	57.64	8.996	60.00	53.50	66.00	29.0	66.0
				Week 44	95	57.77	8.014	60.00	53.00	65.00	32.0	66.0
				W44 CFB	94	1.14	7.730	1.00	-3.00	7.00	-23.0	17.0
	NNRTI	Q4W IM	155	Baseline	151	55.32	9.735	57.00	50.00	63.00	11.0	66.0
				Week 4B	149	59.38	7.202	61.60	56.00	65.00	22.0	66.0
				Week 24	143	62.17	6.485	65.00	60.00	66.00	11.0	66.0
		Current ART	155	Baseline	149	56.46	8.248	58.00	52.00	63.00	32.0	66.0
				Week 24	145	57.20	8.800	58.00	53.00	65.00	11.0	66.0
				Week 44	147	56.20	9.394	58.00	51.00	65.00	29.0	66.0
		W44 CFB	141	-0.41	10.281	0.00	-6.00	5.00	-29.0	24.0		

Note: Summaries at each visit are for actual values, W44 CFB represents the change from Baseline at Week 44, calculated for subjects with both Baseline and Week 44 data.

PPD

21OCT2019 06:52

Table 7.08
 Statistical Analysis of HIVTSQs - Change from Maintenance Baseline in Total
 Treatment Satisfaction Score at Week 44 - Overall - MMRM - ATLAS

Treatment	N	n	Adjusted mean[1]	S.E	Difference [2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q4W IM	308	277	6.21	0.395	5.82 (4.51, 7.13)	<.001	0.7894 (0.08796)	(0.6165, 0.9622)	<.001
Current ART	308	285	0.39	0.536					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, treatment*visit, Maintenance BL (Day 1) Score, sex at birth (female, male), age (<50, >= 50 years), race (white, non-white) and Baseline third agent class (PI, INI, NNRTI) with visit as the repeated factor.

No assumptions were made about the correlations between subject readings of HIVTSQs scores, i.e., the correlation matrix for within-subject errors is unstructured.

[2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

PPD

Table 7.09
 Statistical Analysis of HIVTSQs - Change from Maintenance Baseline in Total
 Treatment Satisfaction Score at Week 44 by Subgroup - MMRM - ATLAS

Subgroup: Age (years) (< 35 vs. >= 35 - < 50 vs. >= 50)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
<35	Q4W IM	80	70	6.28 (0.786)	6.66 (4.11, 9.22)	<.001	0.023	0.4632 (0.16607)	(0.1369, 0.7895)	0.005
	Current ART	80	76	-0.38 (1.041)						
35 - <50	Q4W IM	162	145	5.97 (0.547)	6.54 (4.61, 8.48)	<.001	0.023	0.6144 (0.12428)	(0.3702, 0.8586)	<.001
	Current ART	132	122	-0.57 (0.818)						
>=50	Q4W IM	66	62	6.52 (0.838)	3.99 (1.47, 6.51)	0.002	0.023	0.2832 (0.16619)	(-0.0433, 0.6098)	0.089
	Current ART	96	87	2.52 (0.970)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.09
 Statistical Analysis of HIVTSQs - Change from Maintenance Baseline in Total
 Treatment Satisfaction Score at Week 44 by Subgroup - MMRM - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Female	Q4W IM	99	90	6.69 (0.702)	7.09 (4.82, 9.37)	<.001	0.008	0.5558 (0.14795)	(0.2651, 0.8465)	<.001
	Current ART	104	95	-0.40 (0.939)						
Male	Q4W IM	209	187	5.97 (0.484)	5.19 (3.59, 6.79)	<.001	0.008	0.5789 (0.10452)	(0.3736, 0.7843)	<.001
	Current ART	204	190	0.78 (0.660)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.09
 Statistical Analysis of HIVTSQs - Change from Maintenance Baseline in Total
 Treatment Satisfaction Score at Week 44 by Subgroup - MMRM - ATLAS

Subgroup: Race (White vs. Non-White)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
White	Q4W IM	214	194	5.94 (0.474)	6.32 (4.74, 7.89)	<.001	0.716	0.7129 (0.10379)	(0.5090, 0.9168)	<.001
	Current ART	207	195	-0.38 (0.647)						
Non-White	Q4W IM	94	83	6.82 (0.735)	4.76 (2.41, 7.11)	<.001	0.716	0.3587 (0.15238)	(0.0593, 0.6581)	0.019
	Current ART	101	90	2.07 (0.958)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.09
 Statistical Analysis of HIVTSQs - Change from Maintenance Baseline in Total
 Treatment Satisfaction Score at Week 44 by Subgroup - MMRM - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
North America	Q4W IM	93	85	6.30 (0.732)	4.23 (1.98, 6.48)	<.001	0.209	0.3327 (0.14768)	(0.0425, 0.6228)	0.025
	Current ART	107	100	2.07 (0.914)						
Europe	Q4W IM	145	130	5.79 (0.600)	7.06 (5.20, 8.93)	<.001	0.209	0.6729 (0.12351)	(0.4302, 0.9155)	<.001
	Current ART	146	140	-1.28 (0.776)						
Rest of World	Q4W IM	70	62	6.95 (0.880)	5.10 (2.02, 8.19)	0.001	0.209	0.3034 (0.19577)	(-0.0813, 0.6881)	0.122
	Current ART	55	45	1.84 (1.384)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

Note: MMRM=Mixed Model Repeated Measures.

Table 7.09
 Statistical Analysis of HIVTSQs - Change from Maintenance Baseline in Total
 Treatment Satisfaction Score at Week 44 by Subgroup - MMRM - ATLAS

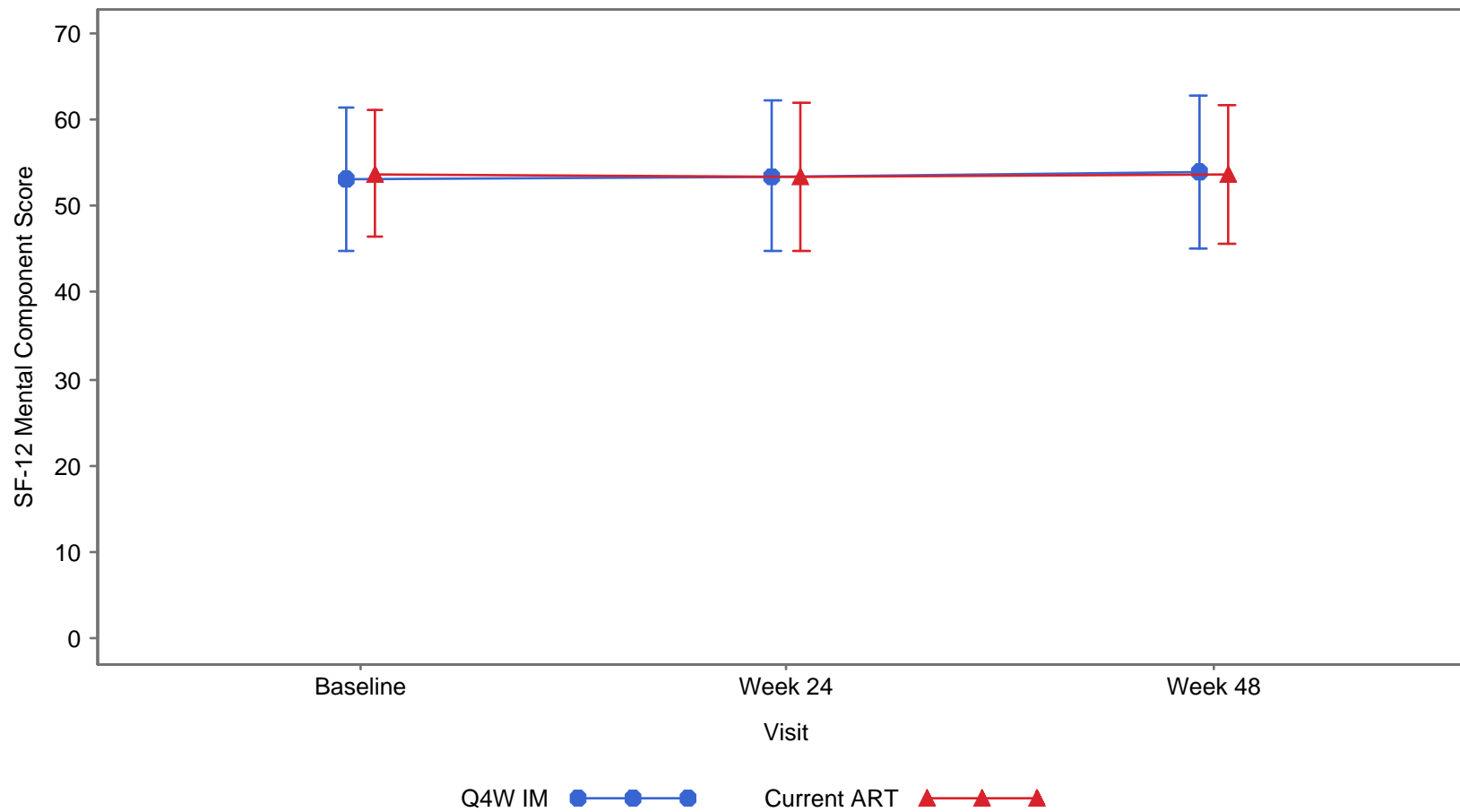
Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

Category	Treatment	N	n	Adjusted mean (S.E) [1]	Difference [2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
PI	Q4W IM	51	47	6.54 (0.964)	8.82 (5.71, 11.93)	<.001	0.006	0.5034 (0.20349)	(0.1035, 0.9032)	0.014
	Current ART	54	50	-2.28 (1.276)						
INI	Q4W IM	102	92	5.57 (0.693)	3.64 (1.38, 5.89)	0.002	0.006	0.2866 (0.14672)	(-0.0017, 0.5748)	0.051
	Current ART	99	94	1.93 (0.925)						
NNRTI	Q4W IM	155	138	6.52 (0.565)	6.22 (4.36, 8.07)	<.001	0.006	0.5958 (0.12107)	(0.3579, 0.8337)	<.001
	Current ART	155	141	0.30 (0.757)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following covariates/factors: treatment, visit, subgroup (if subgroup = region), treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance BL (Day 1) Score, age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), sex at birth (female, male), race (white, non-white), Baseline third agent class (PI, INI, NNRTI), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores, i.e., the correlation matrix for within-subject errors is unstructured.
 [2] Difference:= Q4W IM - Current ART

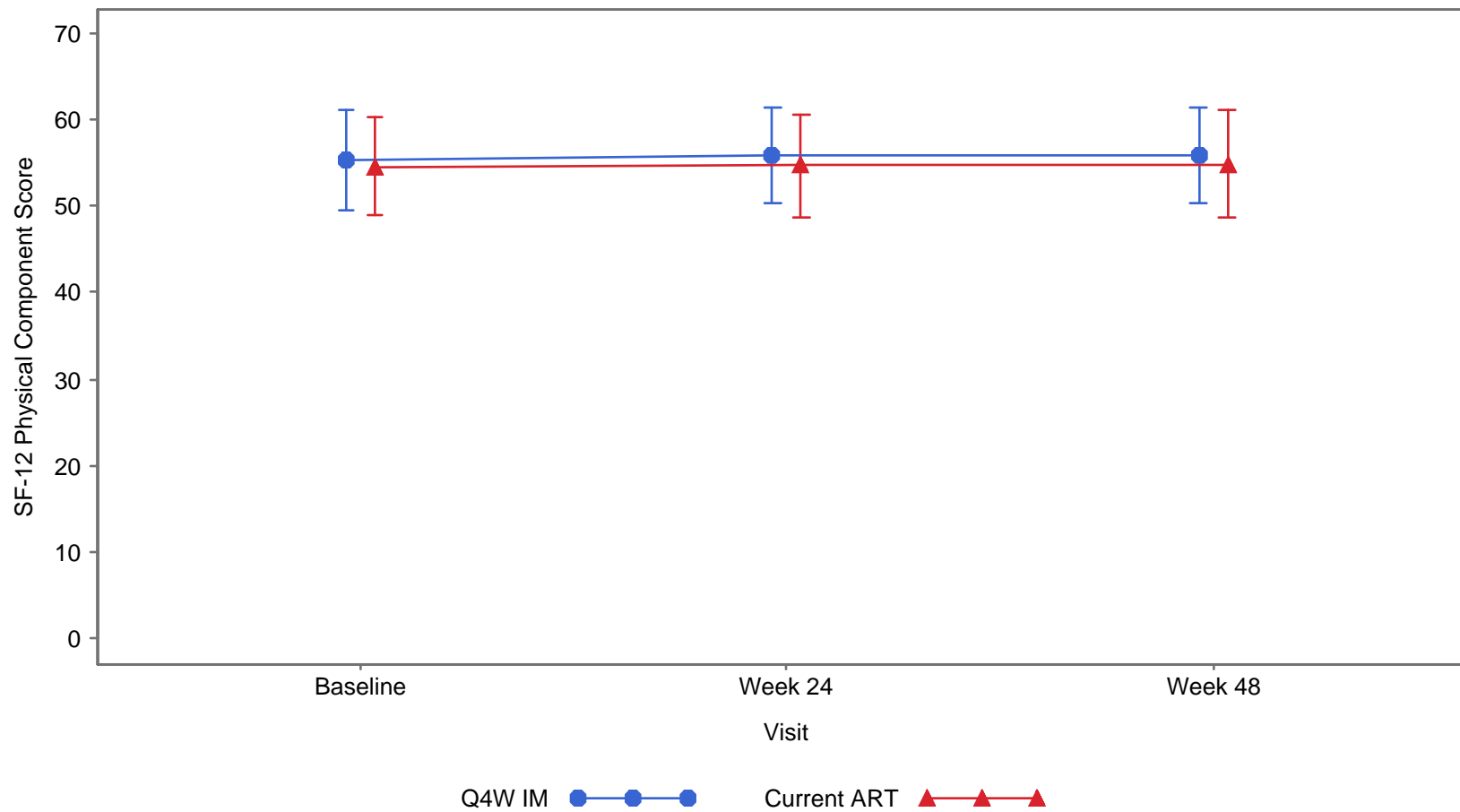
Note: MMRM=Mixed Model Repeated Measures.

Figure 7.01
Line Plot of SF-12 - Mean MCS and PCS Scores Over Time (Maintenance Phase) - ATLAS



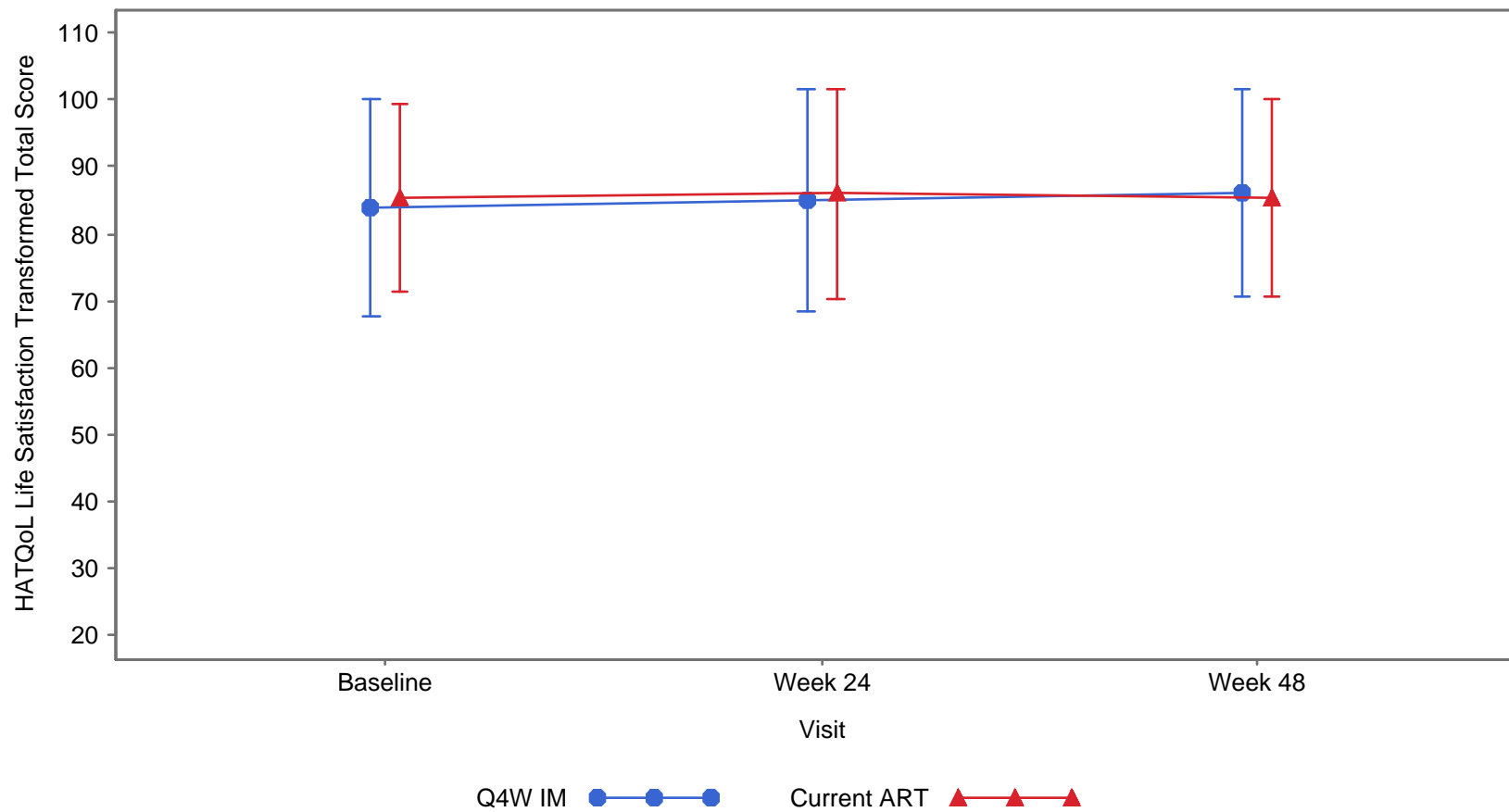
Note: Bars indicate standard deviation (SD).

Figure 7.01
Line Plot of SF-12 - Mean MCS and PCS Scores Over Time (Maintenance Phase) - ATLAS



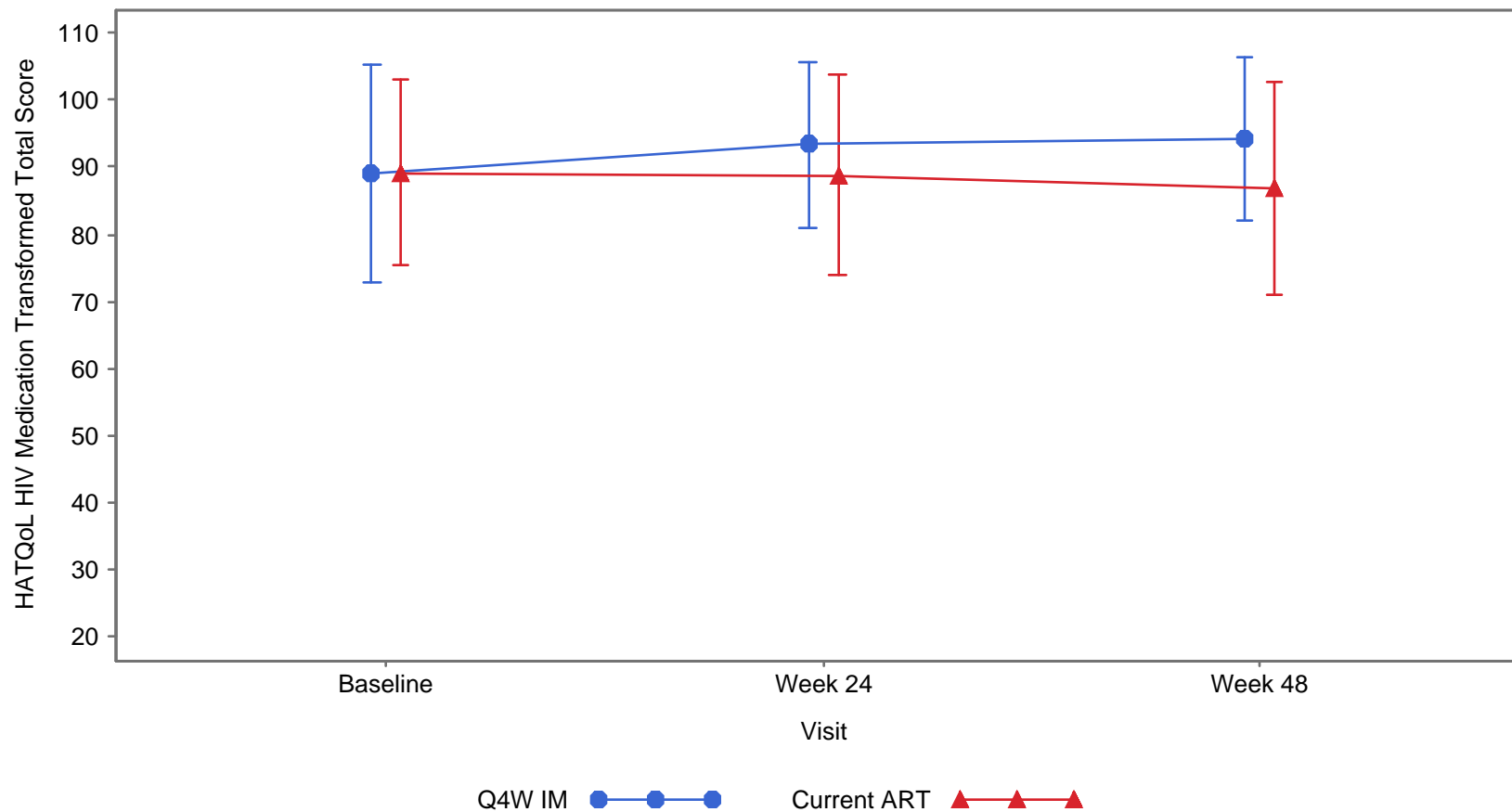
Note: Bars indicate standard deviation (SD).

Figure 7.02
Line Plot of Quality of Life (HATQoL) - Mean Life Satisfaction, HIV Medication, and
Disclosure Worries Over Time (Maintenance Phase) - ATLAS



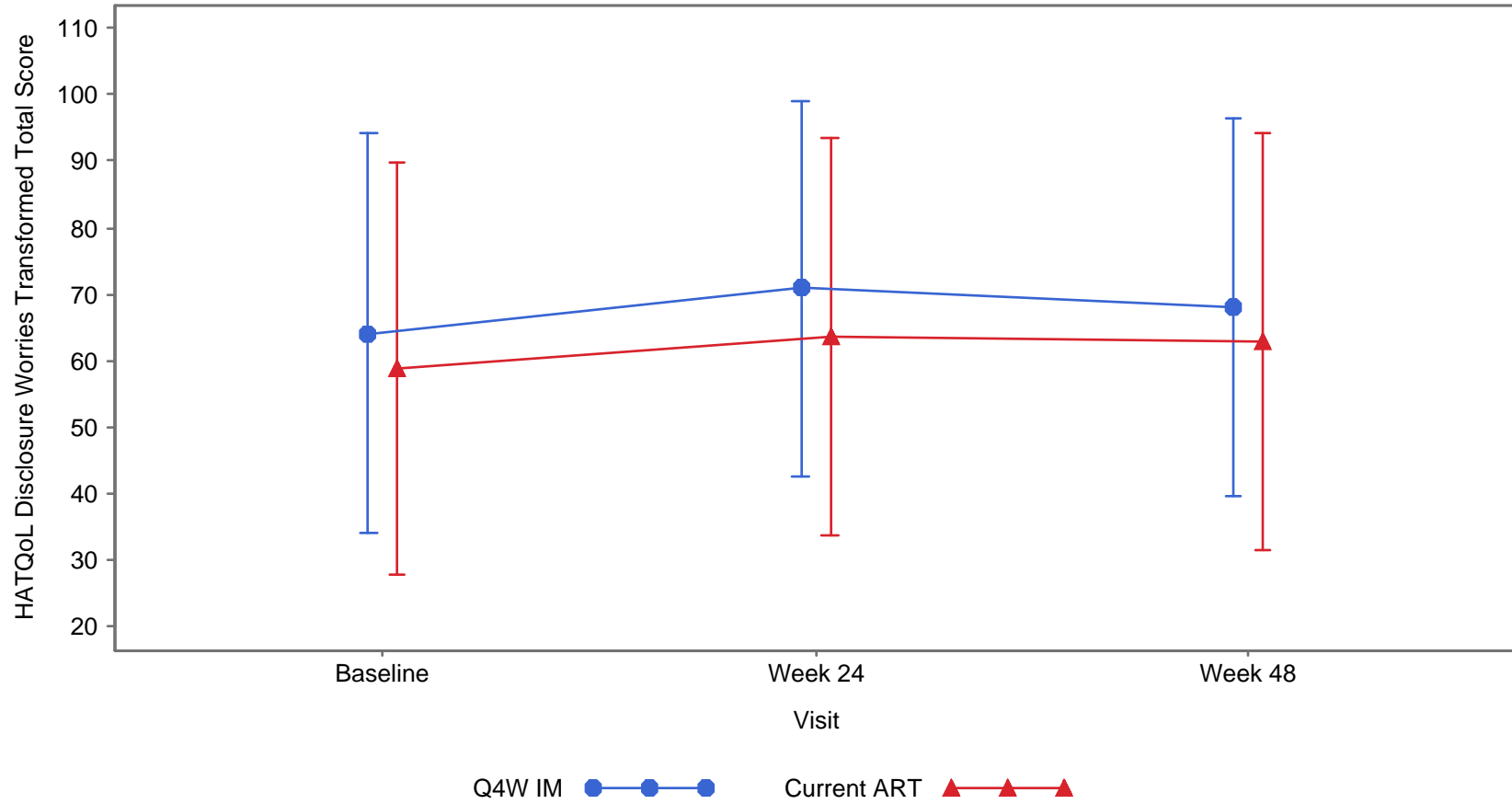
Note: Bars indicate standard deviation (SD).

Figure 7.02
Line Plot of Quality of Life (HATQoL) - Mean Life Satisfaction, HIV Medication, and
Disclosure Worries Over Time (Maintenance Phase) - ATLAS



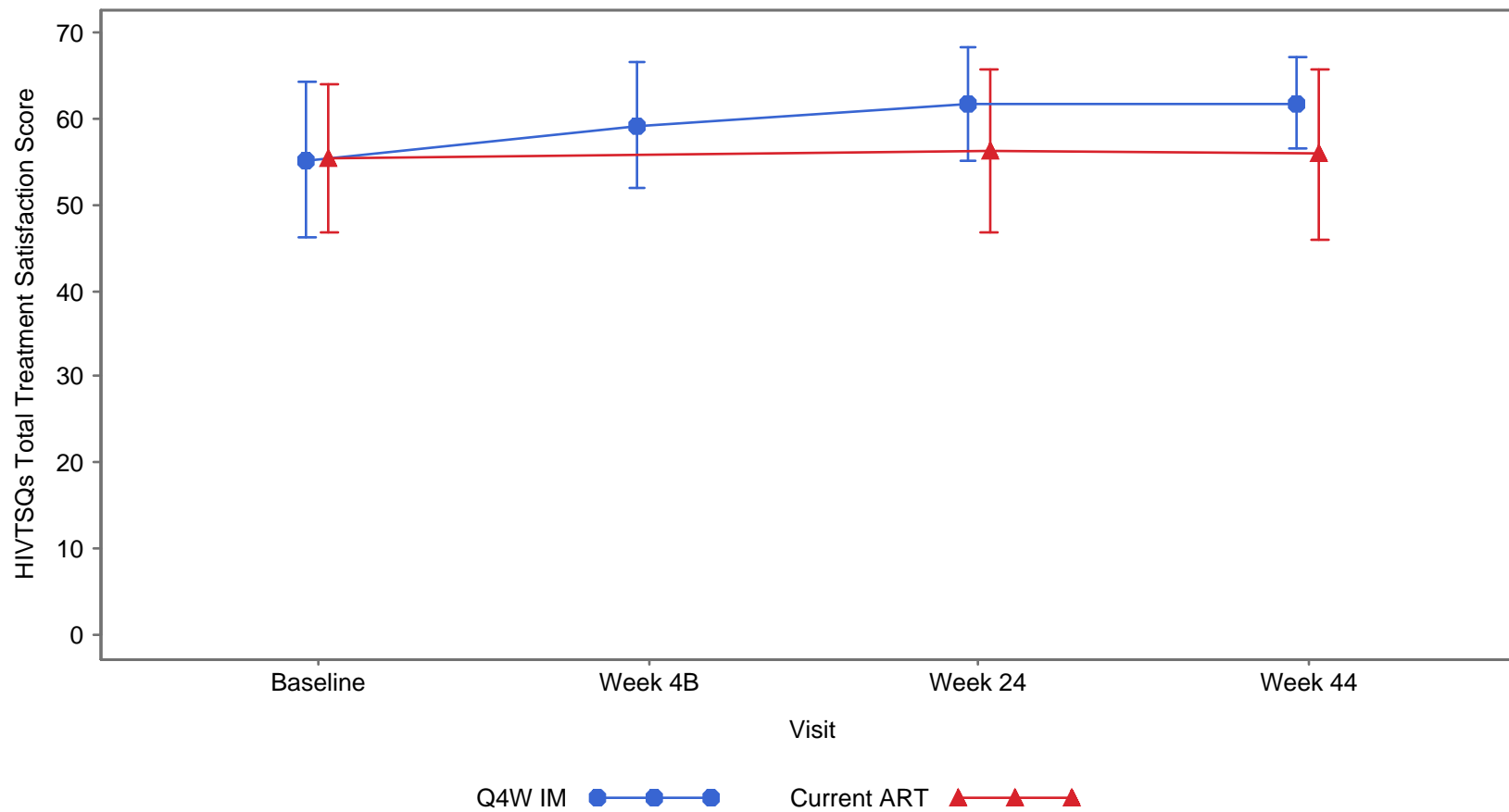
Note: Bars indicate standard deviation (SD).

Figure 7.02
Line Plot of Quality of Life (HATQoL) - Mean Life Satisfaction, HIV Medication, and
Disclosure Worries Over Time (Maintenance Phase) - ATLAS



Note: Bars indicate standard deviation (SD).

Figure 7.03
Line Plot of HIVTSQs - Mean Total Treatment Satisfaction Score Over Time
(Maintenance Phase) - ATLAS



Note: Bars indicate standard deviation (SD).

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Overall					
Any Event	294 (95%)	220 (71%)	8.4000 (4.6545, 15.1595) /<.001	24.0260 (18.4703, 29.5816) /<.001	1.3364 (1.2402, 1.4400) /<.001
Max Grade 1	101 (33%)	115 (37%)	0.8189 (0.5878, 1.1407) /0.237	-4.5455 (-12.0733, 2.9824) /0.237	0.8783 (0.7079, 1.0896) /0.238
Max Grade 2	158 (51%)	81 (26%)	2.9519 (2.1052, 4.1392) /<.001	25.0000 (17.5613, 32.4387) /<.001	1.9506 (1.5712, 2.4217) /<.001
Max Grade 3	27 (9%)	19 (6%)	1.4615 (0.7946, 2.6883) /0.222	2.5974 (-1.5492, 6.7440) /0.220	1.4211 (0.8075, 2.5009) /0.223
Max Grade 4	8 (3%)	4 (1%)	2.0267 (0.6039, 6.8017) /0.253	1.2987 (-0.8817, 3.4791) /0.243	2.0000 (0.6086, 6.5728) /0.254
Max Grade 5	0	1 (<1%)			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Infections and infestations					
Any Event	189 (61%)	164 (53%)	1.3945 (1.0122, 1.9214) /0.042	8.1169 (0.3310, 15.9027) /0.041	1.1524 (1.0048, 1.3218) /0.043
Max Grade 1	125 (41%)	111 (36%)	1.2123 (0.8756, 1.6784) /0.246	4.5455 (-3.1243, 12.2152) /0.245	1.1261 (0.9211, 1.3768) /0.247
Max Grade 2	58 (19%)	50 (16%)	1.1971 (0.7895, 1.8153) /0.397	2.5974 (-3.4046, 8.5994) /0.396	1.1600 (0.8226, 1.6357) /0.397
Max Grade 3	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 4	3 (<1%)	1 (<1%)	3.0197 (0.3124, 29.1910) /0.340	0.6494 (-0.6182, 1.9169) /0.315	3.0000 (0.3138, 28.6819) /0.340
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nasopharyngitis Any Event	52 (17%)	42 (14%)	1.2865 (0.8274, 2.0002) /0.263	3.2468 (-2.4269, 8.9204) /0.262	1.2381 (0.8512, 1.8009) /0.264
Max Grade 1	40 (13%)	39 (13%)	1.0295 (0.6419, 1.6511) /0.904	0.3247 (-4.9562, 5.6055) /0.904	1.0256 (0.6794, 1.5483) /0.904
Max Grade 2	12 (4%)	3 (<1%)	4.1216 (1.1515, 14.7533) /0.030	2.9221 (0.4987, 5.3455) /0.018	4.0000 (1.1400, 14.0349) /0.030
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Upper respiratory tract infection					
Any Event	32 (10%)	25 (8%)	1.3125 (0.7581, 2.2721) /0.332	2.2727 (-2.3004, 6.8459) /0.330	1.2800 (0.7773, 2.1077) /0.332
Max Grade 1	25 (8%)	23 (7%)	1.0946 (0.6070, 1.9741) /0.764	0.6494 (-3.5839, 4.8826) /0.764	1.0870 (0.6310, 1.8724) /0.764
Max Grade 2	7 (2%)	2 (<1%)	3.5581 (0.7333, 17.2660) /0.115	1.6234 (-0.2673, 3.5141) /0.092	3.5000 (0.7329, 16.7144) /0.116
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Influenza					
Any Event	17 (6%)	14 (5%)	1.2268 (0.5938, 2.5348) /0.581	0.9740 (-2.4779, 4.4259) /0.580	1.2143 (0.6094, 2.4197) /0.581
Max Grade 1	16 (5%)	9 (3%)	1.8204 (0.7919, 4.1849) /0.158	2.2727 (-0.8386, 5.3841) /0.152	1.7778 (0.7978, 3.9614) /0.159
Max Grade 2	1 (<1%)	5 (2%)	0.1974 (0.0229, 1.6995) /0.140	-1.2987 (-2.8464, 0.2490) /0.100	0.2000 (0.0235, 1.7020) /0.141
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Respiratory tract infection viral					
Any Event	11 (4%)	17 (6%)	0.6340 (0.2919, 1.3768) /0.249	-1.9481 (-5.2343, 1.3382) /0.245	0.6471 (0.3082, 1.3586) /0.250
Max Grade 1	7 (2%)	13 (4%)	0.5277 (0.2076, 1.3412) /0.179	-1.9481 (-4.7431, 0.8470) /0.172	0.5385 (0.2178, 1.3313) /0.180
Max Grade 2	4 (1%)	4 (1%)	1.0000 (0.2478, 4.0349) />0.999	<0.0001 (-1.7881, 1.7881) />0.999	1.0000 (0.2524, 3.9625) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Bronchitis					
Any Event	13 (4%)	12 (4%)	1.0870 (0.4879, 2.4216) /0.838	0.3247 (-2.7917, 3.4411) /0.838	1.0833 (0.5023, 2.3364) /0.838
Max Grade 1	9 (3%)	7 (2%)	1.2943 (0.4759, 3.5205) /0.613	0.6494 (-1.8623, 3.1610) /0.612	1.2857 (0.4850, 3.4087) /0.613
Max Grade 2	4 (1%)	5 (2%)	0.7974 (0.2121, 2.9980) /0.738	-0.3247 (-2.2196, 1.5702) /0.737	0.8000 (0.2169, 2.9509) /0.738
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Respiratory tract infection Any Event	10 (3%)	12 (4%)	0.8277 (0.3522, 1.9453) /0.665	-0.6494 (-3.5799, 2.2812) /0.664	0.8333 (0.3655, 1.9001) /0.665
Max Grade 1	10 (3%)	11 (4%)	0.9060 (0.3791, 2.1655) /0.824	-0.3247 (-3.1906, 2.5412) /0.824	0.9091 (0.3918, 2.1093) /0.824
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pharyngitis					
Any Event	8 (3%)	12 (4%)	0.6578 (0.2651, 1.6323) /0.366	-1.2987 (-4.0961, 1.4987) /0.363	0.6667 (0.2764, 1.6081) /0.367
Max Grade 1	5 (2%)	9 (3%)	0.5482 (0.1816, 1.6549) /0.286	-1.2987 (-3.6503, 1.0529) /0.279	0.5556 (0.1883, 1.6388) /0.287
Max Grade 2	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9936) />0.999	<0.0001 (-1.5511, 1.5511) />0.999	1.0000 (0.2034, 4.9160) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urinary tract infection					
Any Event	11 (4%)	8 (3%)	1.3889 (0.5509, 3.5017) /0.486	0.9740 (-1.7556, 3.7036) /0.484	1.3750 (0.5608, 3.3715) /0.486
Max Grade 1	10 (3%)	6 (2%)	1.6890 (0.6062, 4.7061) /0.316	1.2987 (-1.2113, 3.8087) /0.311	1.6667 (0.6133, 4.5292) /0.317
Max Grade 2	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gastroenteritis					
Any Event	5 (2%)	10 (3%)	0.4917 (0.1661, 1.4558) /0.200	-1.6234 (-4.0544, 0.8076) /0.191	0.5000 (0.1729, 1.4458) /0.201
Max Grade 1	5 (2%)	9 (3%)	0.5482 (0.1816, 1.6549) /0.286	-1.2987 (-3.6503, 1.0529) /0.279	0.5556 (0.1883, 1.6388) /0.287
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sinusitis					
Any Event	8 (3%)	5 (2%)	1.6160 (0.5227, 4.9961) /0.405	0.9740 (-1.2947, 3.2428) /0.400	1.6000 (0.5293, 4.8362) /0.405
Max Grade 1	7 (2%)	2 (<1%)	3.5581 (0.7333, 17.2660) /0.115	1.6234 (-0.2673, 3.5141) /0.092	3.5000 (0.7329, 16.7144) /0.116
Max Grade 2	1 (<1%)	3 (<1%)	0.3312 (0.0343, 3.2013) /0.340	-0.6494 (-1.9169, 0.6182) /0.315	0.3333 (0.0349, 3.1869) /0.340
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Syphilis					
Any Event	4 (1%)	9 (3%)	0.4371 (0.1332, 1.4348) /0.172	-1.6234 (-3.8898, 0.6431) /0.160	0.4444 (0.1383, 1.4279) /0.173
Max Grade 1	2 (<1%)	7 (2%)	0.2810 (0.0579, 1.3638) /0.115	-1.6234 (-3.5141, 0.2673) /0.092	0.2857 (0.0598, 1.3644) /0.116
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tonsillitis					
Any Event	8 (3%)	4 (1%)	2.0267 (0.6039, 6.8017) /0.253	1.2987 (-0.8817, 3.4791) /0.243	2.0000 (0.6086, 6.5728) /0.254
Max Grade 1	4 (1%)	2 (<1%)	2.0132 (0.3660, 11.0727) /0.421	0.6494 (-0.9009, 2.1996) /0.412	2.0000 (0.3690, 10.8391) /0.421
Max Grade 2	4 (1%)	2 (<1%)	2.0132 (0.3660, 11.0727) /0.421	0.6494 (-0.9009, 2.1996) /0.412	2.0000 (0.3690, 10.8391) /0.421
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lower respiratory tract infection					
Any Event	6 (2%)	5 (2%)	1.2040 (0.3635, 3.9872) /0.761	0.3247 (-1.7668, 2.4161) /0.761	1.2000 (0.3701, 3.8907) /0.761
Max Grade 1	6 (2%)	4 (1%)	1.5099 (0.4219, 5.4043) /0.526	0.6494 (-1.3459, 2.6446) /0.524	1.5000 (0.4275, 5.2631) /0.527
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Conjunctivitis Any Event	7 (2%)	3 (<1%)	2.3643 (0.6057, 9.2289) /0.216	1.2987 (-0.6946, 3.2920) /0.202	2.3333 (0.6090, 8.9401) /0.216
Max Grade 1	6 (2%)	3 (<1%)	2.0199 (0.5006, 8.1502) /0.323	0.9740 (-0.9195, 2.8675) /0.313	2.0000 (0.5047, 7.9250) /0.324
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gonorrhoea					
Any Event	6 (2%)	4 (1%)	1.5099 (0.4219, 5.4043) /0.526	0.6494 (-1.3459, 2.6446) /0.524	1.5000 (0.4275, 5.2631) /0.527
Max Grade 1	6 (2%)	3 (<1%)	2.0199 (0.5006, 8.1502) /0.323	0.9740 (-0.9195, 2.8675) /0.313	2.0000 (0.5047, 7.9250) /0.324
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Oral herpes Any Event	5 (2%)	5 (2%)	1.0000 (0.2866, 3.4896) />0.999	<0.0001 (-1.9959, 1.9959) />0.999	1.0000 (0.2924, 3.4195) />0.999
Max Grade 1	4 (1%)	5 (2%)	0.7974 (0.2121, 2.9980) /0.738	-0.3247 (-2.2196, 1.5702) /0.737	0.8000 (0.2169, 2.9509) /0.738
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Herpes zoster					
Any Event	6 (2%)	3 (<1%)	2.0199 (0.5006, 8.1502) /0.323	0.9740 (-0.9195, 2.8675) /0.313	2.0000 (0.5047, 7.9250) /0.324
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	5 (2%)	2 (<1%)	2.5248 (0.4861, 13.1135) /0.271	0.9740 (-0.6982, 2.6463) /0.254	2.5000 (0.4887, 12.7878) /0.271
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Rhinitis					
Any Event	4 (1%)	5 (2%)	0.7974 (0.2121, 2.9980) /0.738	-0.3247 (-2.2196, 1.5702) /0.737	0.8000 (0.2169, 2.9509) /0.738
Max Grade 1	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 2	1 (<1%)	3 (<1%)	0.3312 (0.0343, 3.2013) /0.340	-0.6494 (-1.9169, 0.6182) /0.315	0.3333 (0.0349, 3.1869) /0.340
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Viral upper respiratory tract infection					
Any Event	6 (2%)	3 (<1%)	2.0199 (0.5006, 8.1502) /0.323	0.9740 (-0.9195, 2.8675) /0.313	2.0000 (0.5047, 7.9250) /0.324
Max Grade 1	5 (2%)	3 (<1%)	1.6777 (0.3974, 7.0820) /0.481	0.6494 (-1.1381, 2.4368) /0.476	1.6667 (0.4018, 6.9133) /0.482
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chlamydial infection					
Any Event	5 (2%)	3 (<1%)	1.6777 (0.3974, 7.0820) /0.481	0.6494 (-1.1381, 2.4368) /0.476	1.6667 (0.4018, 6.9133) /0.482
Max Grade 1	5 (2%)	2 (<1%)	2.5248 (0.4861, 13.1135) /0.271	0.9740 (-0.6982, 2.6463) /0.254	2.5000 (0.4887, 12.7878) /0.271
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastroenteritis viral					
Any Event	5 (2%)	1 (<1%)	5.0660 (0.5884, 43.6169) /0.140	1.2987 (-0.2490, 2.8464) /0.100	5.0000 (0.5876, 42.5483) /0.141
Max Grade 1	5 (2%)	1 (<1%)	5.0660 (0.5884, 43.6169) /0.140	1.2987 (-0.2490, 2.8464) /0.100	5.0000 (0.5876, 42.5483) /0.141
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Genital herpes					
Any Event	2 (<1%)	4 (1%)	0.4967 (0.0903, 2.7321) /0.421	-0.6494 (-2.1996, 0.9009) /0.412	0.5000 (0.0923, 2.7098) /0.421
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Acute sinusitis					
Any Event	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Furuncle					
Any Event	4 (1%)	1 (<1%)	4.0395 (0.4489, 36.3485) /0.213	0.9740 (-0.4410, 2.3891) /0.177	4.0000 (0.4496, 35.5837) /0.214
Max Grade 1	3 (<1%)	1 (<1%)	3.0197 (0.3124, 29.1910) /0.340	0.6494 (-0.6182, 1.9169) /0.315	3.0000 (0.3138, 28.6819) /0.340
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Herpes simplex Any Event	2 (<1%)	3 (<1%)	0.6645 (0.1103, 4.0047) /0.656	-0.3247 (-1.7416, 1.0922) /0.653	0.6667 (0.1122, 3.9620) /0.656
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pneumonia					
Any Event	1 (<1%)	4 (1%)	0.2476 (0.0275, 2.2276) /0.213	-0.9740 (-2.3891, 0.4410) /0.177	0.2500 (0.0281, 2.2240) /0.214
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	3 (<1%)	0.3312 (0.0343, 3.2013) /0.340	-0.6494 (-1.9169, 0.6182) /0.315	0.3333 (0.0349, 3.1869) /0.340
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cystitis					
Any Event	3 (<1%)	1 (<1%)	3.0197 (0.3124, 29.1910) /0.340	0.6494 (-0.6182, 1.9169) /0.315	3.0000 (0.3138, 28.6819) /0.340
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Fungal skin infection					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hordeolum					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Onychomycosis					
Any Event	1 (<1%)	3 (<1%)	0.3312 (0.0343, 3.2013) /0.340	-0.6494 (-1.9169, 0.6182) /0.315	0.3333 (0.0349, 3.1869) /0.340
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Secondary syphilis					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tinea versicolour Any Event	3 (<1%)	1 (<1%)	3.0197 (0.3124, 29.1910) /0.340	0.6494 (-0.6182, 1.9169) /0.315	3.0000 (0.3138, 28.6819) /0.340
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Tooth infection Any Event	3 (<1%)	1 (<1%)	3.0197 (0.3124, 29.1910) /0.340	0.6494 (-0.6182, 1.9169) /0.315	3.0000 (0.3138, 28.6819) /0.340
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Acarodermatitis Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anal chlamydia infection					
Any Event	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Candida infection					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cellulitis					
Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hepatitis A					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site abscess					
Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Oropharyngeal gonococcal infection					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Otitis media					
Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Proctitis gonococcal Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tinea cruris					
Any Event	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 1	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tracheitis					
Any Event	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urethritis gonococcal Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vaginal infection					
Any Event	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anal abscess					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Body tinea					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chronic tonsillitis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ear infection					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Fungal infection					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Genital herpes simplex					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Impetigo					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site cellulitis					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Orchitis					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Otitis media acute					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Paronychia					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pulpitis dental					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Staphylococcal infection					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subcutaneous abscess					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tooth abscess					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urethritis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Urethritis chlamydial					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Viral infection					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Abscess					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Acute hepatitis B					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Acute hepatitis C					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 5	0	0			
Amoebiasis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anal infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Angular cheilitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anorectal human papilloma virus infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Appendicitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Cervicitis human papilloma virus					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Clostridium difficile colitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Conjunctivitis bacterial					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Enteritis infectious					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Epididymitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Folliculitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Gastric infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastroenteritis					
Escherichia coli					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastrointestinal infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastrointestinal viral infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Gingival abscess					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Groin abscess					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Herpes virus infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Infected bite					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Infection parasitic					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Laryngitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Liver abscess					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Localised infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nasal herpes					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Oral candidiasis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Periodontitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Pertussis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pneumonia mycoplasmal Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Post procedural infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Primary syphilis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Proctitis chlamydial					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Proctitis herpes					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Pyelonephritis acute					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rotavirus infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sexually transmitted disease					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Skin candida					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Staphylococcal skin infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tinea infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tinea pedis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tongue fungal infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ureaplasma infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Viral tonsillitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vulvovaginal candidiasis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vulvovaginitis trichomonal					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

General disorders and administration site conditions					
Any Event	252 (82%)	22 (7%)	58.5000 (34.7299, 98.5390) /<.001	74.6753 (69.4959, 79.8547) /<.001	11.4545 (7.6316, 17.1926) /<.001
Max Grade 1	135 (44%)	17 (6%)	13.3577 (7.7970, 22.8843) /<.001	38.3117 (32.2117, 44.4117) /<.001	7.9412 (4.9186, 12.8212) /<.001
Max Grade 2	106 (34%)	5 (2%)	31.8000 (12.7434, 79.3540) /<.001	32.7922 (27.3019, 38.2825) /<.001	21.2000 (8.7676, 51.2617) /<.001
Max Grade 3	11 (4%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site pain					
Any Event	231 (75%)	0	>999 (>999, >999) /NC	73.7807 (61.5500, 86.0113) /<.001	NC
Max Grade 1	130 (42%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	91 (30%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	10 (3%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site nodule					
Any Event	37 (12%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	33 (11%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site induration					
Any Event	30 (10%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	20 (6%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	9 (3%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Pyrexia					
Any Event	21 (7%)	9 (3%)	2.4309 (1.0950, 5.3965) /0.029	3.8961 (0.5105, 7.2817) /0.024	2.3333 (1.0861, 5.0129) /0.030
Max Grade 1	17 (6%)	8 (3%)	2.1907 (0.9311, 5.1546) /0.072	2.9221 (-0.1859, 6.0300) /0.065	2.1250 (0.9309, 4.8507) /0.073
Max Grade 2	3 (<1%)	1 (<1%)	3.0197 (0.3124, 29.1910) /0.340	0.6494 (-0.6182, 1.9169) /0.315	3.0000 (0.3138, 28.6819) /0.340
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Fatigue					
Any Event	22 (7%)	6 (2%)	3.8718 (1.5475, 9.6870) /0.004	5.1948 (1.9306, 8.4590) /0.002	3.6667 (1.5076, 8.9178) /0.004
Max Grade 1	20 (6%)	5 (2%)	4.2083 (1.5588, 11.3615) /0.005	4.8701 (1.7774, 7.9628) /0.002	4.0000 (1.5206, 10.5220) /0.005
Max Grade 2	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site swelling					
Any Event	23 (7%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	16 (5%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	7 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Influenza like illness					
Any Event	11 (4%)	3 (<1%)	3.7654 (1.0401, 13.6320) /0.043	2.5974 (0.2526, 4.9422) /0.030	3.6667 (1.0330, 13.0147) /0.044
Max Grade 1	6 (2%)	3 (<1%)	2.0199 (0.5006, 8.1502) /0.323	0.9740 (-0.9195, 2.8675) /0.313	2.0000 (0.5047, 7.9250) /0.324
Max Grade 2	5 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site erythema					
Any Event	13 (4%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	12 (4%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Injection site bruising					
Any Event	10 (3%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	8 (3%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pain					
Any Event	8 (3%)	1 (<1%)	8.1867 (1.0177, 65.8542) /0.048	2.2727 (0.3862, 4.1593) /0.018	7.9999 (1.0066, 63.5785) /0.049
Max Grade 1	6 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Chills					
Any Event	8 (3%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	5 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site haematoma					
Any Event	7 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	5 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Injection site pruritus					
Any Event	7 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	7 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Asthenia					
Any Event	6 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	6 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Injection site warmth					
Any Event	6 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	6 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site reaction					
Any Event	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Malaise					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Chest pain					
Any Event	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 1	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Cyst					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Discomfort					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Feeling hot					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Oedema peripheral Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chest discomfort Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Feeling of body temperature change					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injection site anaesthesia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injection site discolouration					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injection site discomfort					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Non-cardiac chest pain Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Peripheral swelling					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vessel puncture site pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastrointestinal disorders					
Any Event	74 (24%)	46 (15%)	1.8012 (1.1977, 2.7088) /0.005	9.0909 (2.8771, 15.3047) /0.004	1.6087 (1.1538, 2.2430) /0.005
Max Grade 1	48 (16%)	29 (9%)	1.7761 (1.0871, 2.9020) /0.022	6.1688 (0.9683, 11.3694) /0.020	1.6552 (1.0734, 2.5523) /0.023
Max Grade 2	23 (7%)	15 (5%)	1.5764 (0.8062, 3.0825) /0.183	2.5974 (-1.1969, 6.3917) /0.180	1.5333 (0.8158, 2.8819) /0.184
Max Grade 3	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Diarrhoea					
Any Event	22 (7%)	15 (5%)	1.5026 (0.7641, 2.9546) /0.238	2.2727 (-1.4757, 6.0212) /0.235	1.4667 (0.7757, 2.7732) /0.239
Max Grade 1	14 (5%)	13 (4%)	1.0806 (0.4993, 2.3385) /0.844	0.3247 (-2.9085, 3.5579) /0.844	1.0769 (0.5147, 2.2531) /0.844
Max Grade 2	7 (2%)	2 (<1%)	3.5581 (0.7333, 17.2660) /0.115	1.6234 (-0.2673, 3.5141) /0.092	3.5000 (0.7329, 16.7144) /0.116
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nausea					
Any Event	14 (5%)	5 (2%)	2.8857 (1.0265, 8.1126) /0.044	2.9221 (0.2012, 5.6430) /0.035	2.8000 (1.0210, 7.6787) /0.045
Max Grade 1	10 (3%)	1 (<1%)	10.3020 (1.3107, 80.9747) /0.027	2.9221 (0.8432, 5.0009) /0.006	9.9999 (1.2879, 77.6431) /0.028
Max Grade 2	3 (<1%)	4 (1%)	0.7475 (0.1659, 3.3682) /0.705	-0.3247 (-1.9985, 1.3492) /0.704	0.7500 (0.1693, 3.3231) /0.705
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Toothache					
Any Event	5 (2%)	6 (2%)	0.8306 (0.2508, 2.7507) /0.761	-0.3247 (-2.4161, 1.7668) /0.761	0.8333 (0.2570, 2.7019) /0.761
Max Grade 1	3 (<1%)	4 (1%)	0.7475 (0.1659, 3.3682) /0.705	-0.3247 (-1.9985, 1.3492) /0.704	0.7500 (0.1693, 3.3231) /0.705
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Vomiting					
Any Event	6 (2%)	4 (1%)	1.5099 (0.4219, 5.4043) /0.526	0.6494 (-1.3459, 2.6446) /0.524	1.5000 (0.4275, 5.2631) /0.527
Max Grade 1	4 (1%)	1 (<1%)	4.0395 (0.4489, 36.3485) /0.213	0.9740 (-0.4410, 2.3891) /0.177	4.0000 (0.4496, 35.5837) /0.214
Max Grade 2	1 (<1%)	3 (<1%)	0.3312 (0.0343, 3.2013) /0.340	-0.6494 (-1.9169, 0.6182) /0.315	0.3333 (0.0349, 3.1869) /0.340
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dyspepsia					
Any Event	6 (2%)	2 (<1%)	3.0397 (0.6087, 15.1796) /0.175	1.2987 (-0.4865, 3.0839) /0.154	3.0000 (0.6103, 14.7479) /0.176
Max Grade 1	4 (1%)	2 (<1%)	2.0132 (0.3660, 11.0727) /0.421	0.6494 (-0.9009, 2.1996) /0.412	2.0000 (0.3690, 10.8391) /0.421
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Constipation					
Any Event	4 (1%)	3 (<1%)	1.3377 (0.2969, 6.0274) /0.705	0.3247 (-1.3492, 1.9985) /0.704	1.3333 (0.3009, 5.9078) /0.705
Max Grade 1	4 (1%)	3 (<1%)	1.3377 (0.2969, 6.0274) /0.705	0.3247 (-1.3492, 1.9985) /0.704	1.3333 (0.3009, 5.9078) /0.705
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gastrooesophageal reflux disease Any Event	5 (2%)	2 (<1%)	2.5248 (0.4861, 13.1135) /0.271	0.9740 (-0.6982, 2.6463) /0.254	2.5000 (0.4887, 12.7878) /0.271
Max Grade 1	4 (1%)	1 (<1%)	4.0395 (0.4489, 36.3485) /0.213	0.9740 (-0.4410, 2.3891) /0.177	4.0000 (0.4496, 35.5837) /0.214
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abdominal pain					
Any Event	5 (2%)	1 (<1%)	5.0660 (0.5884, 43.6169) /0.140	1.2987 (-0.2490, 2.8464) /0.100	5.0000 (0.5876, 42.5483) /0.141
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Haemorrhoids					
Any Event	4 (1%)	2 (<1%)	2.0132 (0.3660, 11.0727) /0.421	0.6494 (-0.9009, 2.1996) /0.412	2.0000 (0.3690, 10.8391) /0.421
Max Grade 1	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Proctitis					
Any Event	1 (<1%)	4 (1%)	0.2476 (0.0275, 2.2276) /0.213	-0.9740 (-2.3891, 0.4410) /0.177	0.2500 (0.0281, 2.2240) /0.214
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	3 (<1%)	0.3312 (0.0343, 3.2013) /0.340	-0.6494 (-1.9169, 0.6182) /0.315	0.3333 (0.0349, 3.1869) /0.340
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Flatulence					
Any Event	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Anal fissure					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastritis					
Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Inguinal hernia					
Any Event	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Abdominal discomfort					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Abdominal pain lower					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Abdominal pain upper					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Aphthous ulcer					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Colitis					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dental caries					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Enteritis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Food poisoning Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Odynophagia					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abdominal distension					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Abdominal hernia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anal pruritus					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Anal skin tags					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anorectal discomfort					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Chronic gastritis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dysphagia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Eosinophilic oesophagitis Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Epigastric discomfort					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Functional gastrointestinal disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gingival disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Haemorrhoids thrombosed					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Irritable bowel syndrome					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Lip dry					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Lip swelling					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Mouth ulceration					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Oral disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Oral pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Pancreatitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Pancreatitis acute					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pancreatitis chronic					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Proctitis ulcerative Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rectal haemorrhage Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Steatorrhoea Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Tongue ulceration					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tooth impacted					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Umbilical hernia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Musculoskeletal and connective tissue disorders					
Any Event	69 (22%)	43 (14%)	1.7792 (1.1702, 2.7052) /0.007	8.4416 (2.3865, 14.4966) /0.006	1.6046 (1.1347, 2.2692) /0.007
Max Grade 1	47 (15%)	27 (9%)	1.8741 (1.1340, 3.0973) /0.014	6.4935 (1.3844, 11.6026) /0.013	1.7407 (1.1142, 2.7196) /0.015
Max Grade 2	21 (7%)	15 (5%)	1.4293 (0.7224, 2.8277) /0.305	1.9481 (-1.7536, 5.6497) /0.302	1.4000 (0.7356, 2.6644) /0.305
Max Grade 3	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Back pain					
Any Event	21 (7%)	10 (3%)	2.1805 (1.0093, 4.7107) /0.047	3.5714 (0.1302, 7.0126) /0.042	2.1000 (1.0057, 4.3852) /0.048
Max Grade 1	11 (4%)	9 (3%)	1.2305 (0.5025, 3.0127) /0.650	0.6494 (-2.1495, 3.4482) /0.649	1.2222 (0.5138, 2.9076) /0.650
Max Grade 2	10 (3%)	1 (<1%)	10.3020 (1.3107, 80.9747) /0.027	2.9221 (0.8432, 5.0009) /0.006	9.9999 (1.2879, 77.6431) /0.028
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Arthralgia					
Any Event	6 (2%)	8 (3%)	0.7450 (0.2554, 2.1731) /0.590	-0.6494 (-3.0026, 1.7039) /0.589	0.7500 (0.2633, 2.1361) /0.590
Max Grade 1	5 (2%)	7 (2%)	0.7096 (0.2227, 2.2605) /0.562	-0.6494 (-2.8316, 1.5329) /0.560	0.7143 (0.2292, 2.2261) /0.562
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Musculoskeletal pain					
Any Event	5 (2%)	9 (3%)	0.5482 (0.1816, 1.6549) /0.286	-1.2987 (-3.6503, 1.0529) /0.279	0.5556 (0.1883, 1.6388) /0.287
Max Grade 1	3 (<1%)	5 (2%)	0.5961 (0.1412, 2.5162) /0.481	-0.6494 (-2.4368, 1.1381) /0.476	0.6000 (0.1446, 2.4888) /0.482
Max Grade 2	2 (<1%)	4 (1%)	0.4967 (0.0903, 2.7321) /0.421	-0.6494 (-2.1996, 0.9009) /0.412	0.5000 (0.0923, 2.7098) /0.421
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pain in extremity					
Any Event	6 (2%)	8 (3%)	0.7450 (0.2554, 2.1731) /0.590	-0.6494 (-3.0026, 1.7039) /0.589	0.7500 (0.2633, 2.1361) /0.590
Max Grade 1	3 (<1%)	6 (2%)	0.4951 (0.1227, 1.9977) /0.323	-0.9740 (-2.8675, 0.9195) /0.313	0.5000 (0.1262, 1.9812) /0.324
Max Grade 2	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Myalgia					
Any Event	10 (3%)	3 (<1%)	3.4116 (0.9297, 12.5189) /0.064	2.2727 (0.0098, 4.5357) /0.049	3.3333 (0.9263, 11.9948) /0.065
Max Grade 1	8 (3%)	2 (<1%)	4.0800 (0.8594, 19.3704) /0.077	1.9481 (-0.0419, 3.9380) /0.055	4.0000 (0.8563, 18.6848) /0.078
Max Grade 2	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscle spasms					
Any Event	2 (<1%)	4 (1%)	0.4967 (0.0903, 2.7321) /0.421	-0.6494 (-2.1996, 0.9009) /0.412	0.5000 (0.0923, 2.7098) /0.421
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscle contracture Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 1	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Musculoskeletal chest pain Any Event	3 (<1%)	1 (<1%)	3.0197 (0.3124, 29.1910) /0.340	0.6494 (-0.6182, 1.9169) /0.315	3.0000 (0.3138, 28.6819) /0.340
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Neck pain					
Any Event	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Osteoarthritis					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tendonitis					
Any Event	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Joint swelling					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Spinal pain					
Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Arthropathy					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Bursitis					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Foot deformity					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Intervertebral disc protrusion					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Osteopenia					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Arthritis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Costochondritis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Dupuytren's contracture					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Exostosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Flank pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Intervertebral disc disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Joint effusion					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Muscle tightness					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Musculoskeletal discomfort					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Myositis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Osteonecrosis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Patellofemoral pain syndrome					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Polyarthrititis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Rhabdomyolysis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Scoliosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Spinal osteoarthritis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Synovial cyst					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Temporomandibular joint syndrome					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tenosynovitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nervous system disorders					
Any Event	64 (21%)	35 (11%)	2.0459 (1.3088, 3.1982) /0.002	9.4156 (3.6629, 15.1683) /0.001	1.8286 (1.2498, 2.6754) /0.002
Max Grade 1	48 (16%)	24 (8%)	2.1846 (1.3013, 3.6675) /0.003	7.7922 (2.7554, 12.8290) /0.002	2.0000 (1.2577, 3.1803) /0.003
Max Grade 2	14 (5%)	10 (3%)	1.4190 (0.6204, 3.2457) /0.407	1.2987 (-1.7557, 4.3531) /0.405	1.4000 (0.6316, 3.1033) /0.407
Max Grade 3	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Headache					
Any Event	34 (11%)	17 (6%)	2.1241 (1.1598, 3.8902) /0.015	5.5195 (1.1891, 9.8499) /0.012	2.0000 (1.1420, 3.5026) /0.015
Max Grade 1	26 (8%)	12 (4%)	2.2742 (1.1258, 4.5943) /0.022	4.5455 (0.7626, 8.3283) /0.019	2.1667 (1.1137, 4.2153) /0.023
Max Grade 2	6 (2%)	5 (2%)	1.2040 (0.3635, 3.9872) /0.761	0.3247 (-1.7668, 2.4161) /0.761	1.2000 (0.3701, 3.8907) /0.761
Max Grade 3	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dizziness					
Any Event	9 (3%)	5 (2%)	1.8241 (0.6043, 5.5064) /0.286	1.2987 (-1.0529, 3.6503) /0.279	1.8000 (0.6102, 5.3097) /0.287
Max Grade 1	9 (3%)	4 (1%)	2.2876 (0.6969, 7.5088) /0.172	1.6234 (-0.6431, 3.8898) /0.160	2.2500 (0.7003, 7.2289) /0.173
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sciatica					
Any Event	7 (2%)	1 (<1%)	7.1395 (0.8731, 58.3792) /0.067	1.9481 (0.1665, 3.7296) /0.032	6.9999 (0.8664, 56.5556) /0.068
Max Grade 1	5 (2%)	1 (<1%)	5.0660 (0.5884, 43.6169) /0.140	1.2987 (-0.2490, 2.8464) /0.100	5.0000 (0.5876, 42.5483) /0.141
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Paraesthesia					
Any Event	4 (1%)	2 (<1%)	2.0132 (0.3660, 11.0727) /0.421	0.6494 (-0.9009, 2.1996) /0.412	2.0000 (0.3690, 10.8391) /0.421
Max Grade 1	4 (1%)	2 (<1%)	2.0132 (0.3660, 11.0727) /0.421	0.6494 (-0.9009, 2.1996) /0.412	2.0000 (0.3690, 10.8391) /0.421
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Migraine					
Any Event	4 (1%)	1 (<1%)	4.0395 (0.4489, 36.3485) /0.213	0.9740 (-0.4410, 2.3891) /0.177	4.0000 (0.4496, 35.5837) /0.214
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cervicobrachial syndrome					
Any Event	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Neuralgia					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Syncope					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hypoaesthesia					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Neuropathy peripheral					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Presyncope					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Somnolence					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anterograde amnesia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Autonomic nervous system imbalance					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Burning sensation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Cerebral cyst					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cerebrovascular accident					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cognitive disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Disturbance in attention					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dysaesthesia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Dysgeusia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dystonia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Essential tremor					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Facial paralysis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Intercostal neuralgia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Loss of consciousness					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Memory impairment					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscle contractions involuntary					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Neuromuscular blockade					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Post herpetic neuralgia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Post-traumatic headache					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Seizure					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tension headache					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Respiratory, thoracic and mediastinal disorders					
Any Event	36 (12%)	36 (12%)	1.0000 (0.6117, 1.6349) />0.999	<0.0001 (-5.0743, 5.0743) />0.999	1.0000 (0.6478, 1.5436) />0.999
Max Grade 1	30 (10%)	24 (8%)	1.2770 (0.7282, 2.2393) /0.394	1.9481 (-2.5158, 6.4120) /0.392	1.2500 (0.7484, 2.0879) /0.394
Max Grade 2	6 (2%)	12 (4%)	0.4901 (0.1816, 1.3229) /0.159	-1.9481 (-4.6037, 0.7076) /0.151	0.5000 (0.1901, 1.3152) /0.160
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cough					
Any Event	16 (5%)	14 (5%)	1.1507 (0.5516, 2.4005) /0.708	0.6494 (-2.7498, 4.0485) /0.708	1.1429 (0.5677, 2.3007) /0.708
Max Grade 1	14 (5%)	11 (4%)	1.2857 (0.5743, 2.8786) /0.541	0.9740 (-2.1416, 4.0896) /0.540	1.2727 (0.5871, 2.7591) /0.541
Max Grade 2	2 (<1%)	3 (<1%)	0.6645 (0.1103, 4.0047) /0.656	-0.3247 (-1.7416, 1.0922) /0.653	0.6667 (0.1122, 3.9620) /0.656
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Oropharyngeal pain					
Any Event	9 (3%)	11 (4%)	0.8127 (0.3319, 1.9899) /0.650	-0.6494 (-3.4482, 2.1495) /0.649	0.8182 (0.3439, 1.9464) /0.650
Max Grade 1	9 (3%)	9 (3%)	1.0000 (0.3915, 2.5542) />0.999	<0.0001 (-2.6601, 2.6601) />0.999	1.0000 (0.4024, 2.4852) />0.999
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nasal congestion					
Any Event	2 (<1%)	4 (1%)	0.4967 (0.0903, 2.7321) /0.421	-0.6494 (-2.1996, 0.9009) /0.412	0.5000 (0.0923, 2.7098) /0.421
Max Grade 1	2 (<1%)	4 (1%)	0.4967 (0.0903, 2.7321) /0.421	-0.6494 (-2.1996, 0.9009) /0.412	0.5000 (0.0923, 2.7098) /0.421
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sinus congestion					
Any Event	4 (1%)	2 (<1%)	2.0132 (0.3660, 11.0727) /0.421	0.6494 (-0.9009, 2.1996) /0.412	2.0000 (0.3690, 10.8391) /0.421
Max Grade 1	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Respiratory disorder					
Any Event	2 (<1%)	3 (<1%)	0.6645 (0.1103, 4.0047) /0.656	-0.3247 (-1.7416, 1.0922) /0.653	0.6667 (0.1122, 3.9620) /0.656
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rhinorrhoea					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Catarrh					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dysphonia					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lower respiratory tract congestion					
Any Event	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Asthma					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dyspnoea					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Productive cough					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Respiratory tract congestion					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Rhinitis allergic					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Bronchospasm					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Emphysema					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Lung disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nasal obstruction					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Nasal septum deviation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Pneumonitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Pulmonary mass					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Reflux laryngitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Respiratory distress					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Sinus pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Sleep apnoea syndrome					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Wheezing					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injury, poisoning and procedural complications					
Any Event	37 (12%)	31 (10%)	1.2200 (0.7357, 2.0230) /0.441	1.9481 (-2.9989, 6.8951) /0.440	1.1935 (0.7608, 1.8725) /0.441
Max Grade 1	19 (6%)	19 (6%)	1.0000 (0.5187, 1.9280) />0.999	<0.0001 (-3.7998, 3.7998) />0.999	1.0000 (0.5401, 1.8515) />0.999
Max Grade 2	18 (6%)	9 (3%)	2.0621 (0.9116, 4.6646) /0.082	2.9221 (-0.3030, 6.1471) /0.076	2.0000 (0.9128, 4.3822) /0.083
Max Grade 3	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	1 (<1%)			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ligament sprain Any Event	6 (2%)	2 (<1%)	3.0397 (0.6087, 15.1796) /0.175	1.2987 (-0.4865, 3.0839) /0.154	3.0000 (0.6103, 14.7479) /0.176
Max Grade 1	5 (2%)	1 (<1%)	5.0660 (0.5884, 43.6169) /0.140	1.2987 (-0.2490, 2.8464) /0.100	5.0000 (0.5876, 42.5483) /0.141
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscle strain					
Any Event	3 (<1%)	5 (2%)	0.5961 (0.1412, 2.5162) /0.481	-0.6494 (-2.4368, 1.1381) /0.476	0.6000 (0.1446, 2.4888) /0.482
Max Grade 1	2 (<1%)	4 (1%)	0.4967 (0.0903, 2.7321) /0.421	-0.6494 (-2.1996, 0.9009) /0.412	0.5000 (0.0923, 2.7098) /0.421
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Contusion					
Any Event	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9936) />0.999	<0.0001 (-1.5511, 1.5511) />0.999	1.0000 (0.2034, 4.9160) />0.999
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Arthropod bite					
Any Event	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Procedural pain					
Any Event	1 (<1%)	3 (<1%)	0.3312 (0.0343, 3.2013) /0.340	-0.6494 (-1.9169, 0.6182) /0.315	0.3333 (0.0349, 3.1869) /0.340
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Epicondylitis Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Exposure to communicable disease					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Limb injury					
Any Event	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 1	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Road traffic accident					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Animal bite					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Bone contusion					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hand fracture					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection related reaction					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Radius fracture Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Soft tissue injury					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Thermal burn					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Upper limb fracture					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Buttock injury					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Eye injury					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Facial bones fracture					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Foot fracture Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Humerus fracture Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injury corneal					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Joint dislocation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ligament rupture					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Meniscus injury					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Overdose					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	1 (<1%)			
Post procedural complication					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rib fracture Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Skin abrasion Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Skin injury					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Skull fracture					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Splinter					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tendon rupture					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tooth fracture Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Investigations					
Any Event	36 (12%)	23 (7%)	1.6400 (0.9472, 2.8396) /0.077	4.2208 (-0.4152, 8.8568) /0.074	1.5652 (0.9505, 2.5775) /0.078
Max Grade 1	15 (5%)	10 (3%)	1.5256 (0.6745, 3.4509) /0.310	1.6234 (-1.4905, 4.7373) /0.307	1.5000 (0.6846, 3.2867) /0.311
Max Grade 2	9 (3%)	7 (2%)	1.2943 (0.4759, 3.5205) /0.613	0.6494 (-1.8623, 3.1610) /0.612	1.2857 (0.4850, 3.4087) /0.613
Max Grade 3	7 (2%)	5 (2%)	1.4093 (0.4424, 4.4896) /0.562	0.6494 (-1.5329, 2.8316) /0.560	1.4000 (0.4492, 4.3631) /0.562
Max Grade 4	5 (2%)	1 (<1%)	5.0660 (0.5884, 43.6169) /0.140	1.2987 (-0.2490, 2.8464) /0.100	5.0000 (0.5876, 42.5483) /0.141
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood creatine phosphokinase increased					
Any Event	6 (2%)	4 (1%)	1.5099 (0.4219, 5.4043) /0.526	0.6494 (-1.3459, 2.6446) /0.524	1.5000 (0.4275, 5.2631) /0.527
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Creatinine renal clearance decreased					
Any Event	5 (2%)	3 (<1%)	1.6777 (0.3974, 7.0820) /0.481	0.6494 (-1.1381, 2.4368) /0.476	1.6667 (0.4018, 6.9133) /0.482
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lipase increased					
Any Event	6 (2%)	2 (<1%)	3.0397 (0.6087, 15.1796) /0.175	1.2987 (-0.4865, 3.0839) /0.154	3.0000 (0.6103, 14.7479) /0.176
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 4	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Alanine aminotransferase increased					
Any Event	4 (1%)	1 (<1%)	4.0395 (0.4489, 36.3485) /0.213	0.9740 (-0.4410, 2.3891) /0.177	4.0000 (0.4496, 35.5837) /0.214
Max Grade 1	3 (<1%)	1 (<1%)	3.0197 (0.3124, 29.1910) /0.340	0.6494 (-0.6182, 1.9169) /0.315	3.0000 (0.3138, 28.6819) /0.340
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood pressure increased					
Any Event	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 1	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Aspartate aminotransferase increased					
Any Event	3 (<1%)	1 (<1%)	3.0197 (0.3124, 29.1910) /0.340	0.6494 (-0.6182, 1.9169) /0.315	3.0000 (0.3138, 28.6819) /0.340
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood cholesterol increased					
Any Event	0	4 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Body temperature increased					
Any Event	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Blood creatinine decreased					
Any Event	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood glucose increased					
Any Event	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Electrocardiogram QT prolonged Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Low density lipoprotein increased					
Any Event	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood phosphorus decreased					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood triglycerides increased					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vitamin D decreased					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Weight decreased					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Activated partial thromboplastin time prolonged Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood bilirubin increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood creatinine increased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood triglycerides Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
ECG signs of ventricular hypertrophy					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Glycosylated haemoglobin increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hepatic enzyme increased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Lipids increased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Liver function test abnormal					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Neisseria test positive					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pancreatic enzymes increased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Thyroxine free decreased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Transaminases increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 5	0	0			
Weight increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin and subcutaneous tissue disorders					
Any Event	36 (12%)	22 (7%)	1.7206 (0.9870, 2.9995) /0.056	4.5455 (-0.0531, 9.1440) /0.053	1.6364 (0.9862, 2.7151) /0.057
Max Grade 1	31 (10%)	20 (6%)	1.6116 (0.8971, 2.8951) /0.110	3.5714 (-0.7717, 7.9146) /0.107	1.5500 (0.9037, 2.6584) /0.111
Max Grade 2	5 (2%)	2 (<1%)	2.5248 (0.4861, 13.1135) /0.271	0.9740 (-0.6982, 2.6463) /0.254	2.5000 (0.4887, 12.7878) /0.271
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rash					
Any Event	11 (4%)	4 (1%)	2.8148 (0.8864, 8.9387) /0.079	2.2727 (-0.1550, 4.7005) /0.067	2.7500 (0.8853, 8.5422) /0.080
Max Grade 1	10 (3%)	4 (1%)	2.5503 (0.7912, 8.2212) /0.117	1.9481 (-0.4007, 4.2968) /0.104	2.5000 (0.7926, 7.8854) /0.118
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pruritus					
Any Event	6 (2%)	3 (<1%)	2.0199 (0.5006, 8.1502) /0.323	0.9740 (-0.9195, 2.8675) /0.313	2.0000 (0.5047, 7.9250) /0.324
Max Grade 1	5 (2%)	3 (<1%)	1.6777 (0.3974, 7.0820) /0.481	0.6494 (-1.1381, 2.4368) /0.476	1.6667 (0.4018, 6.9133) /0.482
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Eczema					
Any Event	4 (1%)	1 (<1%)	4.0395 (0.4489, 36.3485) /0.213	0.9740 (-0.4410, 2.3891) /0.177	4.0000 (0.4496, 35.5837) /0.214
Max Grade 1	3 (<1%)	1 (<1%)	3.0197 (0.3124, 29.1910) /0.340	0.6494 (-0.6182, 1.9169) /0.315	3.0000 (0.3138, 28.6819) /0.340
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Acne					
Any Event	3 (<1%)	1 (<1%)	3.0197 (0.3124, 29.1910) /0.340	0.6494 (-0.6182, 1.9169) /0.315	3.0000 (0.3138, 28.6819) /0.340
Max Grade 1	3 (<1%)	1 (<1%)	3.0197 (0.3124, 29.1910) /0.340	0.6494 (-0.6182, 1.9169) /0.315	3.0000 (0.3138, 28.6819) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Rash pruritic					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Alopecia					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dermal cyst					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rash generalised					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Seborrhoeic dermatitis					
Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ecchymosis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Urticaria					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Decubitus ulcer Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dermatitis Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Dermatitis acneiform					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Dermatitis contact					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Intertrigo					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Nail bed bleeding					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Neurodermatitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Onychoclasia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Photosensitivity reaction					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Pruritus generalised					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Purpura					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rash erythematous Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rash maculo-papular Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Sebaceous hyperplasia Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Seborrhoea Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin fissures					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Skin lesion					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin mass					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Stasis dermatitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Psychiatric disorders					
Any Event	32 (10%)	24 (8%)	1.3720 (0.7880, 2.3889) /0.264	2.5974 (-1.9384, 7.1332) /0.262	1.3333 (0.8046, 2.2096) /0.264
Max Grade 1	20 (6%)	14 (5%)	1.4583 (0.7227, 2.9427) /0.292	1.9481 (-1.6553, 5.5515) /0.289	1.4286 (0.7351, 2.7764) /0.293
Max Grade 2	12 (4%)	8 (3%)	1.5203 (0.6126, 3.7727) /0.366	1.2987 (-1.4987, 4.0961) /0.363	1.5000 (0.6218, 3.6183) /0.367
Max Grade 3	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Insomnia					
Any Event	15 (5%)	4 (1%)	3.8908 (1.2764, 11.8598) /0.017	3.5714 (0.8554, 6.2875) /0.010	3.7500 (1.2588, 11.1710) /0.018
Max Grade 1	11 (4%)	4 (1%)	2.8148 (0.8864, 8.9387) /0.079	2.2727 (-0.1550, 4.7005) /0.067	2.7500 (0.8853, 8.5422) /0.080
Max Grade 2	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anxiety					
Any Event	8 (3%)	7 (2%)	1.1467 (0.4106, 3.2020) /0.794	0.3247 (-2.1096, 2.7589) /0.794	1.1429 (0.4196, 3.1128) /0.794
Max Grade 1	6 (2%)	4 (1%)	1.5099 (0.4219, 5.4043) /0.526	0.6494 (-1.3459, 2.6446) /0.524	1.5000 (0.4275, 5.2631) /0.527
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Depression					
Any Event	3 (<1%)	6 (2%)	0.4951 (0.1227, 1.9977) /0.323	-0.9740 (-2.8675, 0.9195) /0.313	0.5000 (0.1262, 1.9812) /0.324
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9936) />0.999	<0.0001 (-1.5511, 1.5511) />0.999	1.0000 (0.2034, 4.9160) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abnormal dreams					
Any Event	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 1	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sleep disorder Any Event	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Depressed mood					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Drug abuse					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Suicidal ideation					
Any Event	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Acute stress disorder					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Stress					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Adjustment disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Affect lability					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Anxiety disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Depression suicidal					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Drug dependence					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Irritability					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Mood altered					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Mood swings					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Panic disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Suicidal behaviour					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Suicide attempt					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tension					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Thinking abnormal					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Metabolism and nutrition disorders					
Any Event	14 (5%)	27 (9%)	0.4956 (0.2546, 0.9645) /0.039	-4.2208 (-8.1433, -0.2982) /0.035	0.5185 (0.2773, 0.9696) /0.040
Max Grade 1	9 (3%)	18 (6%)	0.4849 (0.2144, 1.0970) /0.082	-2.9221 (-6.1471, 0.3030) /0.076	0.5000 (0.2282, 1.0956) /0.083
Max Grade 2	4 (1%)	7 (2%)	0.5658 (0.1639, 1.9527) /0.368	-0.9740 (-3.0642, 1.1162) /0.361	0.5714 (0.1690, 1.9322) /0.368
Max Grade 3	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vitamin D deficiency					
Any Event	8 (3%)	12 (4%)	0.6578 (0.2651, 1.6323) /0.366	-1.2987 (-4.0961, 1.4987) /0.363	0.6667 (0.2764, 1.6081) /0.367
Max Grade 1	7 (2%)	11 (4%)	0.6279 (0.2402, 1.6417) /0.343	-1.2987 (-3.9568, 1.3594) /0.338	0.6364 (0.2500, 1.6199) /0.343
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hypercholesterolemia					
Any Event	1 (<1%)	4 (1%)	0.2476 (0.0275, 2.2276) /0.213	-0.9740 (-2.3891, 0.4410) /0.177	0.2500 (0.0281, 2.2240) /0.214
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Decreased appetite					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dehydration					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Gout					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hyperglycaemia					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hypertriglyceridemia					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hypophosphataemi					
a					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Increased appetite					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Diabetes mellitus					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Diabetic ketoacidosis Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hypokalaemia Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Impaired fasting glucose					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Type 2 diabetes mellitus					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vitamin B12 deficiency					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vitamin B6 deficiency					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Reproductive system and breast disorders					
Any Event	16 (5%)	7 (2%)	2.3562 (0.9554, 5.8106) /0.063	2.9221 (-0.0633, 5.9075) /0.055	2.2857 (0.9538, 5.4778) /0.064
Max Grade 1	10 (3%)	4 (1%)	2.5503 (0.7912, 8.2212) /0.117	1.9481 (-0.4007, 4.2968) /0.104	2.5000 (0.7926, 7.8854) /0.118
Max Grade 2	5 (2%)	3 (<1%)	1.6777 (0.3974, 7.0820) /0.481	0.6494 (-1.1381, 2.4368) /0.476	1.6667 (0.4018, 6.9133) /0.482
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Benign prostatic hyperplasia					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Menorrhagia					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Balanoposthitis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Cervical dysplasia					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Dysmenorrhoea					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Adenomyosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Breast cyst					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Breast mass					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Breast pain Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dysfunctional uterine bleeding Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Genital erythema					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Menometrorrhagia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Menstrual disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Metrorrhagia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Ovarian cyst ruptured					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Penile pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Scrotal mass					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Vaginal discharge					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vaginal haemorrhage Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Blood and lymphatic system disorders					
Any Event	9 (3%)	12 (4%)	0.7425 (0.3083, 1.7884) /0.507	-0.9740 (-3.8390, 1.8909) /0.505	0.7500 (0.3207, 1.7542) /0.507
Max Grade 1	7 (2%)	7 (2%)	1.0000 (0.3465, 2.8857) />0.999	<0.0001 (-2.3538, 2.3538) />0.999	1.0000 (0.3550, 2.8170) />0.999
Max Grade 2	2 (<1%)	3 (<1%)	0.6645 (0.1103, 4.0047) /0.656	-0.3247 (-1.7416, 1.0922) /0.653	0.6667 (0.1122, 3.9620) /0.656
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anaemia					
Any Event	4 (1%)	5 (2%)	0.7974 (0.2121, 2.9980) /0.738	-0.3247 (-2.2196, 1.5702) /0.737	0.8000 (0.2169, 2.9509) /0.738
Max Grade 1	2 (<1%)	3 (<1%)	0.6645 (0.1103, 4.0047) /0.656	-0.3247 (-1.7416, 1.0922) /0.653	0.6667 (0.1122, 3.9620) /0.656
Max Grade 2	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Iron deficiency anaemia					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Lymphadenopathy					
Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anaemia folate deficiency					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Deficiency anaemia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Eosinophilia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Leukocytosis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Microcytic anaemia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Neutropenia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 5	0	0			
Thrombocytopenia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Vascular disorders					
Any Event	13 (4%)	7 (2%)	1.8949 (0.7456, 4.8160) /0.179	1.9481 (-0.8470, 4.7431) /0.172	1.8571 (0.7512, 4.5915) /0.180
Max Grade 1	9 (3%)	4 (1%)	2.2876 (0.6969, 7.5088) /0.172	1.6234 (-0.6431, 3.8898) /0.160	2.2500 (0.7003, 7.2289) /0.173
Max Grade 2	4 (1%)	3 (<1%)	1.3377 (0.2969, 6.0274) /0.705	0.3247 (-1.3492, 1.9985) /0.704	1.3333 (0.3009, 5.9078) /0.705
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hypertension Any Event	9 (3%)	3 (<1%)	3.0602 (0.8205, 11.4138) /0.096	1.9481 (-0.2293, 4.1254) /0.080	3.0000 (0.8200, 10.9756) /0.097
Max Grade 1	5 (2%)	1 (<1%)	5.0660 (0.5884, 43.6169) /0.140	1.2987 (-0.2490, 2.8464) /0.100	5.0000 (0.5876, 42.5483) /0.141
Max Grade 2	4 (1%)	2 (<1%)	2.0132 (0.3660, 11.0727) /0.421	0.6494 (-0.9009, 2.1996) /0.412	2.0000 (0.3690, 10.8391) /0.421
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Deep vein thrombosis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hot flush					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hypertensive crisis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Orthostatic hypotension					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Phlebitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Varicophlebitis Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Varicose vein Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Venous thrombosis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Renal and urinary disorders					
Any Event	12 (4%)	6 (2%)	2.0405 (0.7559, 5.5081) /0.159	1.9481 (-0.7076, 4.6037) /0.151	2.0000 (0.7603, 5.2610) /0.160
Max Grade 1	8 (3%)	3 (<1%)	2.7111 (0.7124, 10.3170) /0.144	1.6234 (-0.4643, 3.7111) /0.127	2.6667 (0.7142, 9.9572) /0.145
Max Grade 2	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9936) />0.999	<0.0001 (-1.5511, 1.5511) />0.999	1.0000 (0.2034, 4.9160) />0.999
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dysuria					
Any Event	4 (1%)	2 (<1%)	2.0132 (0.3660, 11.0727) /0.421	0.6494 (-0.9009, 2.1996) /0.412	2.0000 (0.3690, 10.8391) /0.421
Max Grade 1	4 (1%)	2 (<1%)	2.0132 (0.3660, 11.0727) /0.421	0.6494 (-0.9009, 2.1996) /0.412	2.0000 (0.3690, 10.8391) /0.421
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Pollakiuria					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Renal colic					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Haematuria					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Proteinuria					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Renal impairment Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Chronic kidney disease					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Micturition urgency					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urethral discharge					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Eye disorders					
Any Event	7 (2%)	10 (3%)	0.6930 (0.2603, 1.8448) /0.463	-0.9740 (-3.5602, 1.6121) /0.460	0.7000 (0.2699, 1.8152) /0.463
Max Grade 1	7 (2%)	8 (3%)	0.8721 (0.3123, 2.4352) /0.794	-0.3247 (-2.7589, 2.1096) /0.794	0.8750 (0.3212, 2.3833) /0.794
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chalazion					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Conjunctivitis allergic					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Eye pruritus Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Eyelid oedema Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Vision blurred					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Blepharitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cataract					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Cataract subcapsular					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Conjunctival haemorrhage Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Dry eye Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Eye pain					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Eye swelling					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lacrimation increased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ocular hyperaemia Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vitreous haematoma					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Any Event	9 (3%)	7 (2%)	1.2943 (0.4759, 3.5205) /0.613	0.6494 (-1.8623, 3.1610) /0.612	1.2857 (0.4850, 3.4087) /0.613
Max Grade 1	4 (1%)	4 (1%)	1.0000 (0.2478, 4.0349) />0.999	<0.0001 (-1.7881, 1.7881) />0.999	1.0000 (0.2524, 3.9625) />0.999
Max Grade 2	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Anogenital warts					
Any Event	4 (1%)	3 (<1%)	1.3377 (0.2969, 6.0274) /0.705	0.3247 (-1.3492, 1.9985) /0.704	1.3333 (0.3009, 5.9078) /0.705
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Lipoma					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Basal cell carcinoma					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Fibrous histiocytoma Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Knuckle pads Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Melanocytic naevus					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Papillary thyroid cancer					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Seminoma					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin papilloma					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Squamous cell carcinoma					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Squamous cell carcinoma of skin					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Ear and labyrinth disorders					
Any Event	7 (2%)	2 (<1%)	3.5581 (0.7333, 17.2660) /0.115	1.6234 (-0.2673, 3.5141) /0.092	3.5000 (0.7329, 16.7144) /0.116
Max Grade 1	7 (2%)	2 (<1%)	3.5581 (0.7333, 17.2660) /0.115	1.6234 (-0.2673, 3.5141) /0.092	3.5000 (0.7329, 16.7144) /0.116
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tinnitus					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Vertigo					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Deafness					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Ear discomfort					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ear pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Excessive cerumen production					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vertigo positional					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Immune system disorders					
Any Event	6 (2%)	2 (<1%)	3.0397 (0.6087, 15.1796) /0.175	1.2987 (-0.4865, 3.0839) /0.154	3.0000 (0.6103, 14.7479) /0.176
Max Grade 1	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 2	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Seasonal allergy					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 1	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Allergy to animal					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Drug hypersensitivity					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Mycotic allergy					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cardiac disorders					
Any Event	4 (1%)	1 (<1%)	4.0395 (0.4489, 36.3485) /0.213	0.9740 (-0.4410, 2.3891) /0.177	4.0000 (0.4496, 35.5837) /0.214
Max Grade 1	4 (1%)	1 (<1%)	4.0395 (0.4489, 36.3485) /0.213	0.9740 (-0.4410, 2.3891) /0.177	4.0000 (0.4496, 35.5837) /0.214
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Bradycardia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Cardiovascular disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Palpitations					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Sinus tachycardia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ventricular extrasystoles					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Endocrine disorders					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Max Grade 1	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hypothyroidism					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Hypogonadism					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Thyroid mass					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hepatobiliary disorders					
Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Biliary tract disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cholecystitis acute					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hepatocellular injury					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hyperbilirubinemia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Pregnancy, puerperium and perinatal conditions					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abortion missed					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Abortion spontaneous					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Social circumstances					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Menopause					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Stress at work					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Surgical and medical procedures					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dental implantation					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Overall					
Any Event	35 (11%)	23 (7%)	1.5886 (0.9150, 2.7581) /0.100	3.8961 (-0.7061, 8.4983) /0.097	1.5217 (0.9213, 2.5135) /0.101
Investigations					
Any Event	12 (4%)	6 (2%)	2.0405 (0.7559, 5.5081) /0.159	1.9481 (-0.7076, 4.6037) /0.151	2.0000 (0.7603, 5.2610) /0.160
Lipase increased	5 (2%)	1 (<1%)	5.0660 (0.5884, 43.6169) /0.140	1.2987 (-0.2490, 2.8464) /0.100	5.0000 (0.5876, 42.5483) /0.141
Blood creatine phosphokinase increased	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Blood glucose increased	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood phosphorus decreased	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Blood bilirubin increased	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Blood cholesterol increased	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Blood creatinine increased	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Blood triglycerides	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:23

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood triglycerides increased	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Liver function test abnormal	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Transaminases increased	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Weight decreased	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:23

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

General disorders and administration site conditions					
Any Event	11 (4%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Injection site pain	10 (3%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Injection site induration	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Pyrexia	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.
 Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Infections and infestations					
Any Event	6 (2%)	3 (<1%)	2.0199 (0.5006, 8.1502) /0.323	0.9740 (-0.9195, 2.8675) /0.313	2.0000 (0.5047, 7.9250) /0.324
Hepatitis A	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Acute hepatitis B	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Acute hepatitis C	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Anal abscess	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:23

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Appendicitis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Gastroenteritis Escherichia coli	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Pyelonephritis acute	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Viral infection	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:23

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastrointestinal disorders					
Any Event	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Colitis	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Abdominal pain	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Diarrhoea	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Nausea	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.
 Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pancreatitis acute	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Vomiting	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Any Event	1 (<1%)	3 (<1%)	0.3312 (0.0343, 3.2013) /0.340	-0.6494 (-1.9169, 0.6182) /0.315	0.3333 (0.0349, 3.1869) /0.340
Anogenital warts	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:23

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Papillary thyroid cancer	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Seminoma	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Squamous cell carcinoma	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Metabolism and nutrition disorders					
Any Event	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Hypertriglyceridaemia	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:23

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hypophosphataemia	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Nervous system disorders					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Headache	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Seizure	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:23

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Blood and lymphatic system disorders					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Anaemia	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Neutropenia	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Injury, poisoning and procedural complications					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Animal bite	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Eye injury	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Skull fracture	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Musculoskeletal and connective tissue disorders					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Arthralgia	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Rhabdomyolysis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Psychiatric disorders Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Anxiety	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Anxiety disorder	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Depression	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Suicidal ideation	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Hepatobiliary disorders Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Hepatocellular injury	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Hyperbilirubinaemia	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:23

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Renal and urinary disorders					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Chronic kidney disease	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Reproductive system and breast disorders					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ovarian cyst ruptured	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:23

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Overall					
Any Event	13 (4%)	13 (4%)	1.0000 (0.4559, 2.1935) />0.999	<0.0001 (-3.1756, 3.1756) />0.999	1.0000 (0.4713, 2.1220) />0.999
Infections and infestations					
Any Event	6 (2%)	4 (1%)	1.5099 (0.4219, 5.4043) /0.526	0.6494 (-1.3459, 2.6446) /0.524	1.5000 (0.4275, 5.2631) /0.527
Hepatitis A	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Acute hepatitis B	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:24

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anal abscess	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Appendicitis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Gastroenteritis Escherichia coli	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Liver abscess	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Pneumonia	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:24

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pyelonephritis acute	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Viral infection	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Gastrointestinal disorders					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1446) />0.999	<0.0001 (-1.2686, 1.2686) />0.999	1.0000 (0.1418, 7.0540) />0.999
Colitis	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:24

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pancreatitis acute	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Vomiting	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Any Event	1 (<1%)	2 (<1%)	0.4984 (0.0450, 5.5249) /0.570	-0.3247 (-1.4239, 0.7745) /0.563	0.5000 (0.0456, 5.4855) /0.571
Anogenital warts	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:24

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Papillary thyroid cancer	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Seminoma	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Hepatobiliary disorders					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Cholecystitis acute	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:24

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hepatocellular injury	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Hyperbilirubinaemia	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Injury, poisoning and procedural complications					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Animal bite	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:24

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Eye injury	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Skull fracture	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Pregnancy, puerperium and perinatal conditions					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Abortion missed	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment. NC = Not Calculable.
 Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abortion spontaneous	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
General disorders and administration site conditions					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Chest discomfort	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Investigations					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.
 Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Liver function test abnormal	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Musculoskeletal and connective tissue disorders					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Back pain	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.
 Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Nervous system disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Cerebrovascular accident	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Psychiatric disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Suicidal ideation	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:24

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding deaths)
 - by SOC and Preferred Term (Maintenance Phase) - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Respiratory, thoracic and mediastinal disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Respiratory distress	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:24

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Overall					
Any Event	13 (4%)	5 (2%)	2.6705 (0.9403, 7.5841) /0.065	2.5974 (-0.0548, 5.2496) /0.055	2.6000 (0.9383, 7.2048) /0.066
General disorders and administration site conditions					
Any Event	5 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Injection site pain	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Asthenia	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.
 Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:25

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injection site nodule	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Injection site swelling	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Infections and infestations Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Hepatitis A	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:25

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Acute hepatitis B	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Nervous system disorders					
Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Headache	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Memory impairment	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:25

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Psychiatric disorders					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Anxiety	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Anxiety disorder	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Depression	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Depression suicidal	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:25

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Suicidal ideation	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Gastrointestinal disorders					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Colitis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Diarrhoea	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:25

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nausea	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Investigations Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Blood creatinine increased	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Liver function test abnormal	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:25

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hepatobiliary disorders					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Hepatocellular injury	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Hyperbilirubinaemia	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Injury, poisoning and procedural complications					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:25

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Overdose	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Musculoskeletal and connective tissue disorders					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Myalgia	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Renal and urinary disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:25

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation
 (Maintenance Phase) - by SOC and Preferred Term - ATLAS

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Renal impairment	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk.

RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

06NOV2019 07:25

Table 3.05
Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
Overall and by Subgroup - ATLAS

AE type: Any Event

Subgroup	Category	Q4W IM (N=308)
Overall		250 (81%)
Age (years)	<35	63/ 80 (79%)
	35 - <50	135/162 (83%)
	>=50	52/ 66 (79%)
Sex at Birth	Female	78/ 99 (79%)
	Male	172/209 (82%)
Race	White	181/214 (85%)
	Non-White	69/ 94 (73%)
Region	North America	74/ 93 (80%)
	Europe	123/145 (85%)
	Rest of World	53/ 70 (76%)

Note: "Any Event" represents subjects with any respective AE reported.

PPD

28NOV2019 04:32

Table 3.05
Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
Overall and by Subgroup - ATLAS

AE type: Any Event

Subgroup	Category	Q4W IM (N=308)
Baseline third agent class	PI	41/ 51 (80%)
	INI	84/102 (82%)
	NNRTI	125/155 (81%)

Note: "Any Event" represents subjects with any respective AE reported.

PPD

28NOV2019 04:32

Table 3.05
Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=308)
Overall		239 (78%)
Age (years)	<35	59/ 80 (74%)
	35 - <50	128/162 (79%)
	>=50	52/ 66 (79%)
Sex at Birth	Female	77/ 99 (78%)
	Male	162/209 (78%)
Race	White	173/214 (81%)
	Non-White	66/ 94 (70%)
Region	North America	69/ 93 (74%)
	Europe	118/145 (81%)
	Rest of World	52/ 70 (74%)

Note: "Any Event" represents subjects with any respective AE reported.

PPD

28NOV2019 04:32

Table 3.05
Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=308)
Baseline third agent class	PI	39/ 51 (76%)
	INI	81/102 (79%)
	NNRTI	119/155 (77%)

Note: "Any Event" represents subjects with any respective AE reported.

PPD

28NOV2019 04:32

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=308)	
Overall		11	(4%)
Age (years)	<35	4/ 80	(5%)
	35 - <50	7/162	(4%)
	>=50	0/ 66	
Sex at Birth	Female	1/ 99	(1%)
	Male	10/209	(5%)
Race	White	8/214	(4%)
	Non-White	3/ 94	(3%)
Region	North America	5/ 93	(5%)
	Europe	5/145	(3%)
	Rest of World	1/ 70	(1%)

Note: "Any Event" represents subjects with any respective AE reported.

PPD

28NOV2019 04:32

Table 3.05
Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=308)
Baseline third agent class	PI	2/ 51 (4%)
	INI	3/102 (3%)
	NNRTI	6/155 (4%)

Note: "Any Event" represents subjects with any respective AE reported.

PPD

28NOV2019 04:32

Table 3.05
Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
Overall and by Subgroup - ATLAS

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=308)
Overall		0
Age (years)	<35	0/ 80
	35 - <50	0/162
	>=50	0/ 66
Sex at Birth	Female	0/ 99
	Male	0/209
Race	White	0/214
	Non-White	0/ 94
Region	North America	0/ 93
	Europe	0/145
	Rest of World	0/ 70

Note: "Any Event" represents subjects with any respective AE reported.

PPD

28NOV2019 04:32

Table 3.05
Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
Overall and by Subgroup - ATLAS

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=308)
Baseline third agent class	PI	0/ 51
	INI	0/102
	NNRTI	0/155

Note: "Any Event" represents subjects with any respective AE reported.

PPD

28NOV2019 04:32

Table 3.06
 Analysis of AESI - Proportion of Subjects with any Adverse Event of Hepatotoxicity by Severity
 (Maintenance Phase) - ATLAS

	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Adverse Event of Hepatotoxicity					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1 or 2	0	0	NC	NC	NC
Max Grade 3 or 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Any Serious AE	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.07
Analysis of AESI - Proportion of Subjects with Any Hypersensitivity Reaction (HSR)
Leading to Study Discontinuation by Severity (Maintenance Phase) - ATLAS

No data to report

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS

AE type: Any Event

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		16(5%)	7(2%)	2.3562 (0.9554, 5.8106) /0.063	2.9221 (-0.0633, 5.9075) /0.055	2.2857 (0.9538, 5.4778) /0.064	
Age (years)	<35	4/80(5%)	1/80(1%)	4.1579 (0.4544, 38.0472) /0.207	3.7500 (-1.6106, 9.1106) /0.170	4.0000 (0.4570, 35.0080) /0.210	0.840
	35 - <50	7/162(4%)	3/132(2%)	1.9419 (0.4922, 7.6615) /0.343	2.0483 (-1.9850, 6.0815) /0.320	1.9012 (0.5014, 7.2091) /0.345	
	>=50	5/66(8%)	3/96(3%)	2.5410 (0.5858, 11.0219) /0.213	4.4508 (-2.8202, 11.7218) /0.230	2.4242 (0.5998, 9.7976) /0.214	

Note: "Any Event" represents subjects with any respective AE reported.

OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS

AE type: Any Event

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Sex at Birth	Female	6/99(6%)	4/104(4%)	1.6129 (0.4412, 5.8962) /0.470	2.2145 (-3.7648, 8.1937) /0.468	1.5758 (0.4584, 5.4173) /0.470	0.420
	Male	10/209(5%)	3/204(1%)	3.3668 (0.9130, 12.4159) /0.068	3.3141 (-0.0179, 6.6461) /0.051	3.2536 (0.9085, 11.6518) /0.070	
Race	White	11/214(5%)	2/207(<1%)	5.5542 (1.2159, 25.3717) /0.027	4.1740 (0.9292, 7.4188) /0.012	5.3201 (1.1937, 23.7115) /0.028	0.086
	Non-White	5/94(5%)	5/101(5%)	1.0787 (0.3021, 3.8513) /0.907	0.3687 (-5.8344, 6.5717) /0.907	1.0745 (0.3213, 3.5937) /0.907	

Note: "Any Event" represents subjects with any respective AE reported.

OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS

AE type: Any Event

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	6/93(6%)	2/107(2%)	3.6207 (0.7127, 18.3935) /0.121	4.5825 (-1.0314, 10.1963) /0.110	3.4516 (0.7138, 16.6905) /0.123	0.782
	Europe	5/145(3%)	3/146(2%)	1.7024 (0.3992, 7.2589) /0.472	1.3935 (-2.3636, 5.1506) /0.467	1.6782 (0.4086, 6.8929) /0.473	
	Rest of World	5/70(7%)	2/55(4%)	2.0385 (0.3801, 10.9315) /0.406	3.5065 (-4.2956, 11.3086) /0.378	1.9643 (0.3961, 9.7422) /0.409	

Note: "Any Event" represents subjects with any respective AE reported.

OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS

AE type: Any Event

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Baseline third agent class	PI	2/51(4%)	1/54(2%)	2.1633 (0.1901, 24.6136) /0.534	2.0697 (-4.3575, 8.4970) /0.528	2.1176 (0.1980, 22.6477) /0.535	0.963
	INI	8/102(8%)	3/99(3%)	2.7234 (0.7011, 10.5795) /0.148	4.8128 (-1.4020, 11.0276) /0.129	2.5882 (0.7070, 9.4758) /0.151	
	NNRTI	6/155(4%)	3/155(2%)	2.0403 (0.5010, 8.3085) /0.320	1.9355 (-1.7963, 5.6673) /0.309	2.0000 (0.5093, 7.8542) /0.321	

Note: "Any Event" represents subjects with any respective AE reported.

OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		16(5%)	7(2%)	2.3562 (0.9554, 5.8106) /0.063	2.9221 (-0.0633, 5.9075) /0.055	2.2857 (0.9538, 5.4778) /0.064	
Age (years)	<35	4/80(5%)	1/80(1%)	4.1579 (0.4544, 38.0472) /0.207	3.7500 (-1.6106, 9.1106) /0.170	4.0000 (0.4570, 35.0080) /0.210	0.840
	35 - <50	7/162(4%)	3/132(2%)	1.9419 (0.4922, 7.6615) /0.343	2.0483 (-1.9850, 6.0815) /0.320	1.9012 (0.5014, 7.2091) /0.345	
	>=50	5/66(8%)	3/96(3%)	2.5410 (0.5858, 11.0219) /0.213	4.4508 (-2.8202, 11.7218) /0.230	2.4242 (0.5998, 9.7976) /0.214	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Sex at Birth	Female	6/99(6%)	4/104(4%)	1.6129 (0.4412, 5.8962) /0.470	2.2145 (-3.7648, 8.1937) /0.468	1.5758 (0.4584, 5.4173) /0.470	0.420
	Male	10/209(5%)	3/204(1%)	3.3668 (0.9130, 12.4159) /0.068	3.3141 (-0.0179, 6.6461) /0.051	3.2536 (0.9085, 11.6518) /0.070	
Race	White	11/214(5%)	2/207(<1%)	5.5542 (1.2159, 25.3717) /0.027	4.1740 (0.9292, 7.4188) /0.012	5.3201 (1.1937, 23.7115) /0.028	0.086
	Non-White	5/94(5%)	5/101(5%)	1.0787 (0.3021, 3.8513) /0.907	0.3687 (-5.8344, 6.5717) /0.907	1.0745 (0.3213, 3.5937) /0.907	

Note: "Any Event" represents subjects with any respective AE reported.

OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	6/93(6%)	2/107(2%)	3.6207 (0.7127, 18.3935) /0.121	4.5825 (-1.0314, 10.1963) /0.110	3.4516 (0.7138, 16.6905) /0.123	0.782
	Europe	5/145(3%)	3/146(2%)	1.7024 (0.3992, 7.2589) /0.472	1.3935 (-2.3636, 5.1506) /0.467	1.6782 (0.4086, 6.8929) /0.473	
	Rest of World	5/70(7%)	2/55(4%)	2.0385 (0.3801, 10.9315) /0.406	3.5065 (-4.2956, 11.3086) /0.378	1.9643 (0.3961, 9.7422) /0.409	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Baseline third agent class	PI	2/51(4%)	1/54(2%)	2.1633 (0.1901, 24.6136) /0.534	2.0697 (-4.3575, 8.4970) /0.528	2.1176 (0.1980, 22.6477) /0.535	0.963
	INI	8/102(8%)	3/99(3%)	2.7234 (0.7011, 10.5795) /0.148	4.8128 (-1.4020, 11.0276) /0.129	2.5882 (0.7070, 9.4758) /0.151	
	NNRTI	6/155(4%)	3/155(2%)	2.0403 (0.5010, 8.3085) /0.320	1.9355 (-1.7963, 5.6673) /0.309	2.0000 (0.5093, 7.8542) /0.321	

Note: "Any Event" represents subjects with any respective AE reported.

OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		0	0	NC	NC	NC	
Age (years)	<35	0/80	0/80	NC	NC	NC	NC
	35 - <50	0/162	0/132	NC	NC	NC	
	>=50	0/66	0/96	NC	NC	NC	
Sex at Birth	Female	0/99	0/104	NC	NC	NC	NC
	Male	0/209	0/204	NC	NC	NC	
Race	White	0/214	0/207	NC	NC	NC	NC
	Non-White	0/94	0/101	NC	NC	NC	
Region	North America	0/93	0/107	NC	NC	NC	NC
	Europe	0/145	0/146	NC	NC	NC	
	Rest of World	0/70	0/55	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08

Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Baseline third agent class	PI	0/51	0/54	NC	NC	NC	NC
	INI	0/102	0/99	NC	NC	NC	
	NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.

OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		0	0	NC	NC	NC	
Age (years)	<35	0/80	0/80	NC	NC	NC	NC
	35 - <50	0/162	0/132	NC	NC	NC	
	>=50	0/66	0/96	NC	NC	NC	
Sex at Birth	Female	0/99	0/104	NC	NC	NC	NC
	Male	0/209	0/204	NC	NC	NC	
Race	White	0/214	0/207	NC	NC	NC	NC
	Non-White	0/94	0/101	NC	NC	NC	
Region	North America	0/93	0/107	NC	NC	NC	NC
	Europe	0/145	0/146	NC	NC	NC	
	Rest of World	0/70	0/55	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Baseline third agent class	PI	0/51	0/54	NC	NC	NC	NC
	INI	0/102	0/99	NC	NC	NC	
	NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.09
 Analysis of AESI - Proportion of Subjects with Any Event of QT Prolongation
 by Severity (Maintenance Phase) - ATLAS

	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Event of QT Prolongation					
Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1 or 2	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3 or 4	0	0	NC	NC	NC
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Any Event

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		30(10%)	25(8%)	1.2216 (0.7006, 2.1300) /0.480	1.6234 (-2.8785, 6.1253) /0.480	1.2000 (0.7230, 1.9918) /0.481	
Age (years)	<35	9/80(11%)	8/80(10%)	1.1408 (0.4167, 3.1236) /0.798	1.2500 (-8.2978, 10.7978) /0.797	1.1250 (0.4571, 2.7686) /0.798	0.999
	35 - <50	17/162(10%)	12/132(9%)	1.1724 (0.5388, 2.5513) /0.688	1.4029 (-5.4032, 8.2091) /0.686	1.1543 (0.5719, 2.3300) /0.689	
	>=50	4/66(6%)	5/96(5%)	1.1742 (0.3032, 4.5467) /0.816	0.8523 (-6.4205, 8.1250) /0.818	1.1636 (0.3245, 4.1722) /0.816	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

PPD

18NOV2019 12:06

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Any Event

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Sex at Birth	Female	6/99(6%)	7/104(7%)	0.8940 (0.2897, 2.7590) /0.846	-0.6702 (-7.3992, 6.0589) /0.845	0.9004 (0.3135, 2.5863) /0.846	0.548
	Male	24/209(11%)	18/204(9%)	1.3405 (0.7039, 2.5528) /0.373	2.6597 (-3.1568, 8.4763) /0.370	1.3014 (0.7288, 2.3241) /0.373	
Race	White	23/214(11%)	16/207(8%)	1.4375 (0.7364, 2.8059) /0.288	3.0182 (-2.5004, 8.5368) /0.284	1.3905 (0.7564, 2.5559) /0.289	0.373
	Non-White	7/94(7%)	9/101(9%)	0.8225 (0.2935, 2.3045) /0.710	-1.4641 (-9.1477, 6.2195) /0.709	0.8357 (0.3242, 2.1543) /0.710	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

PPD

18NOV2019 12:06

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Any Event

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	14/93(15%)	14/107(13%)	1.1772 (0.5294, 2.6178) /0.689	1.9697 (-7.7076, 11.6469) /0.690	1.1505 (0.5790, 2.2863) /0.689	0.180
	Europe	9/145(6%)	10/146(7%)	0.9000 (0.3546, 2.2842) /0.825	-0.6424 (-6.3178, 5.0330) /0.824	0.9062 (0.3794, 2.1646) /0.825	
	Rest of World	7/70(10%)	1/55(2%)	6.0000 (0.7155, 50.3169) /0.099	8.1818 (0.3168, 16.0468) /0.041	5.5000 (0.6973, 43.3827) /0.106	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

PPD

18NOV2019 12:06

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Any Event

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Baseline third agent class	PI	6/51(12%)	1/54(2%)	7.0667 (0.8199, 60.9071) /0.075	9.9129 (0.3672, 19.4585) /0.042	6.3529 (0.7920, 50.9601) /0.082	0.122
	INI	10/102(10%)	11/99(11%)	0.8696 (0.3518, 2.1492) /0.762	-1.3072 (-9.7704, 7.1561) /0.762	0.8824 (0.3923, 1.9844) /0.762	
	NNRTI	14/155(9%)	13/155(8%)	1.0846 (0.4922, 2.3898) /0.840	0.6452 (-5.6323, 6.9226) /0.840	1.0769 (0.5235, 2.2154) /0.840	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

PPD

18NOV2019 12:06

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		30(10%)	23(7%)	1.3372 (0.7579, 2.3592) /0.316	2.2727 (-2.1526, 6.6980) /0.314	1.3043 (0.7757, 2.1934) /0.316	
Age (years)	<35	9/80(11%)	8/80(10%)	1.1408 (0.4167, 3.1236) /0.798	1.2500 (-8.2978, 10.7978) /0.797	1.1250 (0.4571, 2.7686) /0.798	0.933
	35 - <50	17/162(10%)	10/132(8%)	1.4303 (0.6316, 3.2391) /0.391	2.9181 (-3.6126, 9.4487) /0.381	1.3852 (0.6566, 2.9223) /0.392	
	>=50	4/66(6%)	5/96(5%)	1.1742 (0.3032, 4.5467) /0.816	0.8523 (-6.4205, 8.1250) /0.818	1.1636 (0.3245, 4.1722) /0.816	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

PPD

18NOV2019 12:06

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Sex at Birth	Female	6/99(6%)	7/104(7%)	0.8940 (0.2897, 2.7590) /0.846	-0.6702 (-7.3992, 6.0589) /0.845	0.9004 (0.3135, 2.5863) /0.846	0.432
	Male	24/209(11%)	16/204(8%)	1.5243 (0.7844, 2.9621) /0.214	3.6401 (-2.0426, 9.3229) /0.209	1.4641 (0.8016, 2.6743) /0.215	
Race	White	23/214(11%)	14/207(7%)	1.6601 (0.8294, 3.3224) /0.152	3.9844 (-1.3935, 9.3623) /0.146	1.5891 (0.8410, 3.0027) /0.154	0.266
	Non-White	7/94(7%)	9/101(9%)	0.8225 (0.2935, 2.3045) /0.710	-1.4641 (-9.1477, 6.2195) /0.709	0.8357 (0.3242, 2.1543) /0.710	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

PPD

18NOV2019 12:06

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	14/93(15%)	12/107(11%)	1.4030 (0.6137, 3.2071) /0.422	3.8388 (-5.5723, 13.2499) /0.424	1.3423 (0.6539, 2.7556) /0.422	0.189
	Europe	9/145(6%)	10/146(7%)	0.9000 (0.3546, 2.2842) /0.825	-0.6424 (-6.3178, 5.0330) /0.824	0.9062 (0.3794, 2.1646) /0.825	
	Rest of World	7/70(10%)	1/55(2%)	6.0000 (0.7155, 50.3169) /0.099	8.1818 (0.3168, 16.0468) /0.041	5.5000 (0.6973, 43.3827) /0.106	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Baseline third agent class	PI	6/51(12%)	1/54(2%)	7.0667 (0.8199, 60.9071) /0.075	9.9129 (0.3672, 19.4585) /0.042	6.3529 (0.7920, 50.9601) /0.082	0.153
	INI	10/102(10%)	10/99(10%)	0.9674 (0.3841, 2.4364) /0.944	-0.2971 (-8.5759, 7.9817) /0.944	0.9706 (0.4225, 2.2298) /0.944	
	NNRTI	14/155(9%)	12/155(8%)	1.1832 (0.5288, 2.6475) /0.682	1.2903 (-4.8794, 7.4600) /0.682	1.1667 (0.5576, 2.4409) /0.682	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

PPD

18NOV2019 12:06

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Age (years)	<35	0/80	0/80	NC	NC	NC	NC
	35 - <50	0/162	2/132(2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
	>=50	0/66	0/96	NC	NC	NC	
Sex at Birth	Female	0/99	0/104	NC	NC	NC	NC
	Male	0/209	2/204(<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Race	White	0/214	2/207(<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
	Non-White	0/94	0/101	NC	NC	NC	
Region	North America	0/93	2/107(2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
	Europe	0/145	0/146	NC	NC	NC	
	Rest of World	0/70	0/55	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Maximum Toxicity Grade 3 or 4

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Baseline third agent class	PI	0/51	0/54	NC	NC	NC	NC
	INI	0/102	1/99(1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
	NNRTI	0/155	1/155(<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Age (years)	<35	0/80	0/80	NC	NC	NC	NC
	35 - <50	0/162	1/132(<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
	>=50	0/66	0/96	NC	NC	NC	
Sex at Birth	Female	0/99	0/104	NC	NC	NC	NC
	Male	0/209	1/204(<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Race	White	0/214	1/207(<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
	Non-White	0/94	0/101	NC	NC	NC	
Region	North America	0/93	1/107(<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
	Europe	0/145	0/146	NC	NC	NC	
	Rest of World	0/70	0/55	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference(in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

PPD

18NOV2019 12:06

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS

AE type: Serious Adverse Events

Subgroup	Category	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Baseline third agent class	PI	0/51	0/54	NC	NC	NC	NC
	INI	0/102	0/99	NC	NC	NC	
	NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any respective AE reported.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Neuropsychiatric adverse event: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

PPD

18NOV2019 12:06

Table 3.11
 Analysis of AESI - Proportion of Subjects with Any Seizure or Seizure-like Adverse Event
 by Severity (Maintenance Phase) - ATLAS

	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Seizure or Seizure-like Adverse Event					
Any Event	3 (<1%)	2 (<1%)	1.5049 (0.2497, 9.0698) /0.656	0.3247 (-1.0922, 1.7416) /0.653	1.5000 (0.2524, 8.9145) /0.656
Max Grade 1 or 2	3 (<1%)	1 (<1%)	3.0197 (0.3124, 29.1910) /0.340	0.6494 (-0.6182, 1.9169) /0.315	3.0000 (0.3138, 28.6819) /0.340
Max Grade 3 or 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.12
 Analysis of AESI - Proportion of Subjects with any Event of Weight Gain by Severity
 (Maintenance Phase) - ATLAS

	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Event of Weight Gain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 1 or 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3 or 4	0	0	NC	NC	NC
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.13
 Analysis of AESI - Proportion of Subjects with Any Event of Rhabdomyolysis by Severity
 (Maintenance Phase) - ATLAS

	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Event of Rhabdomyolysis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1 or 2	0	0	NC	NC	NC
Max Grade 3 or 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.14
 Analysis of AESI - Proportion of Subjects with Any Event of Pancreatitis by Severity
 (Maintenance Phase) - ATLAS

	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Event of Pancreatitis					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1 or 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Max Grade 3 or 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Any Serious AE	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.15
 Analysis of AESI - Proportion of Subjects with Any Event Indicating an Impact on Creatinine
 by Severity (Maintenance Phase) - ATLAS

	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Event Indicating an Impact on Creatinine					
Any Event	2 (<1%)	1 (<1%)	2.0065 (0.1810, 22.2442) /0.570	0.3247 (-0.7745, 1.4239) /0.563	2.0000 (0.1823, 21.9420) /0.571
Max Grade 1 or 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3 or 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3247 (-11.0397, 11.6891) /0.955	>999 (>999, >999) /NC
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.16
 Analysis of AESI - Proportion of Subjects with Any Event of Relevance to Safety in Pregnancy
 by Severity (Maintenance Phase) - ATLAS

	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Event of Relevance to Safety in Pregnancy					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 1 or 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999
Max Grade 3 or 4	0	0	NC	NC	NC
Any Serious AE	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0598) />0.999	<0.0001 (-0.8985, 0.8985) />0.999	1.0000 (0.0628, 15.9157) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to
 unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	74/ 80 (93%)	55/ 80 (69%)	5.6061 (2.1532, 14.5960) /<.001	23.7500 (12.0677, 35.4323) /<.001	1.3455 (1.1461, 1.5795) /<.001	0.499
35 - <50	157/162 (97%)	92/132 (70%)	13.6522 (5.2031, 35.8215) /<.001	27.2166 (18.9367, 35.4965) /<.001	1.3905 (1.2385, 1.5612) /<.001	
>=50	63/ 66 (95%)	73/ 96 (76%)	6.6164 (1.8967, 23.0807) /0.003	19.4129 (9.5056, 29.3202) /<.001	1.2553 (1.1089, 1.4210) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
<35	50/ 80 (63%)	42/ 80 (53%)	1.5079 (0.8028, 2.8325) /0.202	10.0000 (-5.2410, 25.2410) /0.198	1.1905 (0.9099, 1.5576) /0.204	0.683
35 - <50	97/162 (60%)	73/132 (55%)	1.2061 (0.7574, 1.9206) /0.430	4.5735 (-6.7801, 15.9272) /0.430	1.0827 (0.8878, 1.3205) /0.433	
>=50	42/ 66 (64%)	49/ 96 (51%)	1.6786 (0.8837, 3.1885) /0.114	12.5947 (-2.7246, 27.9140) /0.107	1.2468 (0.9540, 1.6294) /0.106	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
<35	11/ 80 (14%)	10/ 80 (13%)	1.1159 (0.4453, 2.7964) /0.815	1.2500 (-9.2126, 11.7126) /0.815	1.1000 (0.4951, 2.4440) /0.815	0.862
35 - <50	27/162 (17%)	18/132 (14%)	1.2667 (0.6636, 2.4177) /0.474	3.0303 (-5.1677, 11.2283) /0.469	1.2222 (0.7049, 2.1191) /0.475	
>=50	14/ 66 (21%)	14/ 96 (15%)	1.5769 (0.6958, 3.5741) /0.275	6.6288 (-5.5005, 18.7581) /0.284	1.4545 (0.7434, 2.8460) /0.274	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
<35	8/ 80 (10%)	5/ 80 (6%)	1.6667 (0.5208, 5.3336) /0.389	3.7500 (-4.6970, 12.1970) /0.384	1.6000 (0.5469, 4.6810) /0.391	0.782
35 - <50	18/162 (11%)	11/132 (8%)	1.3750 (0.6252, 3.0238) /0.428	2.7778 (-3.9787, 9.5343) /0.420	1.3333 (0.6529, 2.7229) /0.430	
>=50	6/ 66 (9%)	9/ 96 (9%)	0.9667 (0.3269, 2.8582) /0.951	-0.2841 (-9.3450, 8.7768) /0.951	0.9697 (0.3624, 2.5949) /0.951	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza <35	3/ 80 (4%)	2/ 80 (3%)	1.5195 (0.2470, 9.3470) /0.652	1.2500 (-4.1385, 6.6385) /0.649	1.5000 (0.2575, 8.7374) /0.652	0.891
35 - <50	9/162 (6%)	7/132 (5%)	1.0504 (0.3804, 2.9002) /0.924	0.2525 (-4.9490, 5.4541) /0.924	1.0476 (0.4009, 2.7378) /0.924	
>=50	5/ 66 (8%)	5/ 96 (5%)	1.4918 (0.4142, 5.3725) /0.541	2.3674 (-5.4113, 10.1462) /0.551	1.4545 (0.4384, 4.8260) /0.540	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
<35	4/ 80 (5%)	5/ 80 (6%)	0.7895 (0.2041, 3.0543) /0.732	-1.2500 (-8.3875, 5.8875) /0.731	0.8000 (0.2229, 2.8708) /0.732	0.063
35 - <50	4/162 (2%)	11/132 (8%)	0.2785 (0.0866, 0.8960) /0.032	-5.8642 (-11.1501, -0.5783) /0.030	0.2963 (0.0966, 0.9091) /0.033	
>=50	3/ 66 (5%)	1/ 96 (1%)	4.5238 (0.4602, 44.4703) /0.196	3.5038 (-1.9164, 8.9240) /0.205	4.3636 (0.4639, 41.0452) /0.198	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis <35	0/ 80	4/ 80 (5%)	<0.0001 (<0.0001, -) />0.999	-7.1707 (-30.0734, 15.7321) /0.539	<0.0001 (<0.0001, -) />0.999	0.015
35 - <50	10/162 (6%)	3/132 (2%)	2.8289 (0.7623, 10.4989) /0.120	3.9001 (-0.5941, 8.3943) /0.089	2.7160 (0.7631, 9.6673) /0.123	
>=50	3/ 66 (5%)	5/ 96 (5%)	0.8667 (0.1999, 3.7579) /0.848	-0.6629 (-7.3718, 6.0460) /0.846	0.8727 (0.2159, 3.5272) /0.848	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
<35	0/ 80	5/ 80 (6%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.008
35 - <50	10/162 (6%)	5/132 (4%)	1.6710 (0.5568, 5.0154) /0.360	2.3850 (-2.5486, 7.3185) /0.343	1.6296 (0.5711, 4.6505) /0.361	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis						
<35	3/ 80 (4%)	3/ 80 (4%)	1.0000 (0.1957, 5.1099) />0.999	<0.0001 (-5.8875, 5.8875) />0.999	1.0000 (0.2080, 4.8067) />0.999	0.400
35 - <50	3/162 (2%)	7/132 (5%)	0.3369 (0.0854, 1.3294) /0.120	-3.4512 (-7.8014, 0.8990) /0.120	0.3492 (0.0921, 1.3241) /0.122	
>=50	2/ 66 (3%)	2/ 96 (2%)	1.4687 (0.2017, 10.6968) /0.704	0.9470 (-4.0796, 5.9735) /0.712	1.4545 (0.2101, 10.0688) /0.704	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
<35	7/ 80 (9%)	1/ 80 (1%)	7.5753 (0.9099, 63.0679) /0.061	7.5000 (0.8467, 14.1533) /0.027	7.0000 (0.8813, 55.5985) /0.066	0.057
35 - <50	3/162 (2%)	3/132 (2%)	0.8113 (0.1610, 4.0877) /0.800	-0.4209 (-3.7032, 2.8615) /0.802	0.8148 (0.1672, 3.9706) /0.800	
>=50	1/ 66 (2%)	4/ 96 (4%)	0.3538 (0.0387, 3.2391) /0.358	-2.6515 (-7.6177, 2.3147) /0.295	0.3636 (0.0416, 3.1809) /0.361	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
<35	3/ 80 (4%)	4/ 80 (5%)	0.7403 (0.1603, 3.4191) /0.700	-1.2500 (-7.5856, 5.0856) /0.699	0.7500 (0.1734, 3.2441) /0.700	0.465
35 - <50	2/162 (1%)	4/132 (3%)	0.4000 (0.0721, 2.2187) /0.295	-1.7957 (-5.1785, 1.5870) /0.298	0.4074 (0.0758, 2.1898) /0.295	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis						
<35	2/ 80 (3%)	4/ 80 (5%)	0.4872 (0.0867, 2.7385) /0.414	-2.5000 (-8.3748, 3.3748) /0.404	0.5000 (0.0942, 2.6530) /0.416	0.045
35 - <50	5/162 (3%)	0/132	>999 (>999, >999) /NC	5.3329 (-12.2992, 22.9649) /0.553	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis <35	2/ 80 (3%)	3/ 80 (4%)	0.6581 (0.1070, 4.0484) /0.652	-1.2500 (-6.6385, 4.1385) /0.649	0.6667 (0.1145, 3.8833) /0.652	0.385
35 - <50	1/162 (<1%)	5/132 (4%)	0.1578 (0.0182, 1.3674) /0.094	-3.1706 (-6.6434, 0.3022) /0.074	0.1630 (0.0193, 1.3778) /0.096	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
<35	6/ 80 (8%)	1/ 80 (1%)	6.4054 (0.7532, 54.4759) /0.089	6.2500 (-0.0142, 12.5142) /0.051	6.0000 (0.7390, 48.7136) /0.094	0.196
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
<35	0/ 80	0/ 80	NC	NC	NC	0.562
35 - <50	5/162 (3%)	2/132 (2%)	2.0701 (0.3951, 10.8459) /0.389	1.5713 (-1.8104, 4.9529) /0.362	2.0370 (0.4017, 10.3309) /0.390	
>=50	1/ 66 (2%)	3/ 96 (3%)	0.4769 (0.0485, 4.6873) /0.525	-1.6098 (-6.1705, 2.9508) /0.489	0.4848 (0.0515, 4.5606) /0.527	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
<35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.057
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	4/ 66 (6%)	0/ 96	>999 (>999, >999) /NC	8.1845 (-13.2031, 29.5721) /0.453	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea <35	2/ 80 (3%)	1/ 80 (1%)	2.0256 (0.1800, 22.7973) /0.568	1.2500 (-2.9490, 5.4490) /0.560	2.0000 (0.1850, 21.6178) /0.568	0.730
35 - <50	3/162 (2%)	1/132 (<1%)	2.4717 (0.2541, 24.0434) /0.436	1.0943 (-1.4548, 3.6434) /0.400	2.4444 (0.2573, 23.2264) /0.437	
>=50	1/ 66 (2%)	2/ 96 (2%)	0.7231 (0.0642, 8.1413) /0.793	-0.5682 (-4.6728, 3.5364) /0.786	0.7273 (0.0673, 7.8574) /0.793	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes <35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.423
35 - <50	4/162 (2%)	2/132 (2%)	1.6456 (0.2967, 9.1272) /0.569	0.9540 (-2.2167, 4.1246) /0.555	1.6296 (0.3032, 8.7592) /0.569	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster						
<35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	0.039
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	4/ 66 (6%)	0/ 96	>999 (>999, >999) /NC	8.1845 (-13.2031, 29.5721) /0.453	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.184
35 - <50	3/162 (2%)	3/132 (2%)	0.8113 (0.1610, 4.0877) /0.800	-0.4209 (-3.7032, 2.8615) /0.802	0.8148 (0.1672, 3.9706) /0.800	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
<35	2/ 80 (3%)	2/ 80 (3%)	1.0000 (0.1374, 7.2786) />0.999	<0.0001 (-4.8383, 4.8383) />0.999	1.0000 (0.1444, 6.9262) />0.999	0.273
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
<35	2/ 80 (3%)	1/ 80 (1%)	2.0256 (0.1800, 22.7973) /0.568	1.2500 (-2.9490, 5.4490) /0.560	2.0000 (0.1850, 21.6178) /0.568	0.984
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	4/162 (2%)	1/132 (<1%)	3.3165 (0.3662, 30.0363) /0.286	1.7116 (-1.0989, 4.5220) /0.233	3.2593 (0.3687, 28.8100) /0.288	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
<35	0/ 80	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	2/162 (1%)	2/132 (2%)	0.8125 (0.1129, 5.8471) /0.837	-0.2806 (-2.9702, 2.4090) /0.838	0.8148 (0.1163, 5.7067) /0.837	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute sinusitis						
<35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	0.966
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	3/132 (2%)	0.5375 (0.0885, 3.2652) /0.500	-1.0382 (-4.0968, 2.0205) /0.506	0.5432 (0.0921, 3.2031) /0.500	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.444
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	2/ 96 (2%)	0.7231 (0.0642, 8.1413) /0.793	-0.5682 (-4.6728, 3.5364) /0.786	0.7273 (0.0673, 7.8574) /0.793	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum <35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Onychomycosis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea versicolour						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.522
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	>0.999
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Candida infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Cellulitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Hepatitis A						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site abscess						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	
Otitis media						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea cruris <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
<35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic tonsillitis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impetigo <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site cellulitis						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media acute						
<35	0/ 80	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pulpitis dental						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal infection						
<35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth abscess						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis chlamydial						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Abscess						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis C						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amoebiasis						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Anal infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal human papilloma virus infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Appendicitis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervicitis human papilloma virus						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Clostridium difficile colitis						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Conjunctivitis bacterial						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Enteritis infectious						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epididymitis <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Folliculitis <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastric infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis Escherichia coli						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal infection						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal viral infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival abscess						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Groin abscess						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes virus infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Infected bite						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Infection parasitic <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver abscess						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Localised infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Nasal herpes						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral candidiasis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Periodontitis						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Pertussis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia mycoplasmal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Primary syphilis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Proctitis chlamydial						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis herpes						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis acute						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotavirus infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted disease						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin candida						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Tinea pedis						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue fungal infection						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Ureaplasma infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Viral tonsillitis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal candidiasis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginitis trichomonal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	63/ 80 (79%)	9/ 80 (11%)	29.2353 (12.1714, 70.2221) /<.001	67.5000 (56.1731, 78.8269) /<.001	7.0000 (3.7434, 13.0897) /<.001	0.073
35 - <50	137/162 (85%)	5/132 (4%)	139.1915 (51.7168, 374.6226) /<.001	80.7800 (74.3339, 87.2261) /<.001	22.3259 (9.4260, 52.8798) /<.001	
>=50	52/ 66 (79%)	8/ 96 (8%)	40.8571 (16.0582, 103.9536) /<.001	70.4545 (59.1479, 81.7612) /<.001	9.4545 (4.8131, 18.5720) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain <35	57/ 80 (71%)	0/ 80	>999 (>999, >999) /NC	70.2130 (46.0751, 94.3509) /<.001	NC	NC
35 - <50	127/162 (78%)	0/132	>999 (>999, >999) /NC	NC	NC	
>=50	47/ 66 (71%)	0/ 96	>999 (>999, >999) /NC	70.1770 (47.2767, 93.0772) /<.001	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
<35	7/ 80 (9%)	0/ 80	>999 (>999, >999) /NC	10.7500 (-12.3859, 33.8858) /0.362	>999 (>999, >999) /NC	NC
35 - <50	21/162 (13%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	9/ 66 (14%)	0/ 96	>999 (>999, >999) /NC	15.4033 (-6.5932, 37.3999) /0.170	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
<35	5/ 80 (6%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35 - <50	18/162 (11%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	7/ 66 (11%)	0/ 96	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia <35	7/ 80 (9%)	6/ 80 (8%)	1.1826 (0.3792, 3.6881) /0.773	1.2500 (-7.2148, 9.7148) /0.772	1.1667 (0.4101, 3.3188) /0.773	0.130
35 - <50	11/162 (7%)	1/132 (<1%)	9.5430 (1.2158, 74.9080) /0.032	6.0325 (1.8858, 10.1793) /0.004	8.9630 (1.1723, 68.5303) /0.035	
>=50	3/ 66 (5%)	2/ 96 (2%)	2.2381 (0.3636, 13.7778) /0.385	2.4621 (-3.3186, 8.2428) /0.404	2.1818 (0.3748, 12.7011) /0.385	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue <35	4/ 80 (5%)	4/ 80 (5%)	1.0000 (0.2413, 4.1450) />0.999	<0.0001 (-6.7541, 6.7541) />0.999	1.0000 (0.2590, 3.8606) />0.999	0.070
35 - <50	12/162 (7%)	1/132 (<1%)	10.4800 (1.3445, 81.6861) /0.025	6.6498 (2.3543, 10.9454) /0.002	9.7778 (1.2880, 74.2265) /0.027	
>=50	6/ 66 (9%)	1/ 96 (1%)	9.5000 (1.1160, 80.8685) /0.039	8.0492 (0.8224, 15.2761) /0.029	8.7273 (1.0755, 70.8192) /0.043	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
<35	7/ 80 (9%)	0/ 80	>999 (>999, >999) /NC	10.7500 (-12.3859, 33.8858) /0.362	>999 (>999, >999) /NC	>0.999
35 - <50	11/162 (7%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	5/ 66 (8%)	0/ 96	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.017
35 - <50	7/162 (4%)	0/132	>999 (>999, >999) /NC	6.5203 (-11.1455, 24.1861) /0.469	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	3/ 96 (3%)	0.4769 (0.0485, 4.6873) /0.525	-1.6098 (-6.1705, 2.9508) /0.489	0.4848 (0.0515, 4.5606) /0.527	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	9/162 (6%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site bruising						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
35 - <50	5/162 (3%)	0/132	>999 (>999, >999) /NC	5.3329 (-12.2992, 22.9649) /0.553	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.405
35 - <50	5/162 (3%)	0/132	>999 (>999, >999) /NC	5.3329 (-12.2992, 22.9649) /0.553	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	1/ 96 (1%)	2.9687 (0.2636, 33.4293) /0.378	1.9886 (-2.6187, 6.5960) /0.398	2.9091 (0.2693, 31.4296) /0.379	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haematoma						
<35	4/ 80 (5%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	5/162 (3%)	0/132	>999 (>999, >999) /NC	5.3329 (-12.2992, 22.9649) /0.553	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	5/162 (3%)	0/132	>999 (>999, >999) /NC	5.3329 (-12.2992, 22.9649) /0.553	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site warmth						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	3/ 66 (5%)	0/ 96	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site reaction						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.200
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cyst <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Discomfort <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Oedema peripheral						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest discomfort						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling of body temperature change						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site anaesthesia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-cardiac chest pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral swelling						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vessel puncture site pain						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	18/ 80 (23%)	12/ 80 (15%)	1.6452 (0.7337, 3.6888) /0.227	7.5000 (-4.5397, 19.5397) /0.222	1.5000 (0.7742, 2.9064) /0.230	0.562
35 - <50	41/162 (25%)	17/132 (13%)	2.2922 (1.2327, 4.2624) /0.009	12.4299 (3.6277, 21.2320) /0.006	1.9651 (1.1723, 3.2941) /0.010	
>=50	15/ 66 (23%)	17/ 96 (18%)	1.3668 (0.6275, 2.9770) /0.431	5.0189 (-7.6511, 17.6890) /0.438	1.2834 (0.6907, 2.3847) /0.430	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea <35	9/ 80 (11%)	5/ 80 (6%)	1.9014 (0.6079, 5.9475) /0.269	5.0000 (-3.7223, 13.7223) /0.261	1.8000 (0.6309, 5.1354) /0.272	0.425
35 - <50	11/162 (7%)	5/132 (4%)	1.8503 (0.6264, 5.4658) /0.265	3.0022 (-2.0588, 8.0633) /0.245	1.7926 (0.6388, 5.0304) /0.268	
>=50	2/ 66 (3%)	5/ 96 (5%)	0.5688 (0.1070, 3.0234) /0.508	-2.1780 (-8.2492, 3.8931) /0.482	0.5818 (0.1163, 2.9096) /0.510	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea <35	4/ 80 (5%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.240
35 - <50	7/162 (4%)	3/132 (2%)	1.9419 (0.4922, 7.6615) /0.343	2.0483 (-1.9850, 6.0815) /0.320	1.9012 (0.5014, 7.2091) /0.345	
>=50	3/ 66 (5%)	2/ 96 (2%)	2.2381 (0.3636, 13.7778) /0.385	2.4621 (-3.3186, 8.2428) /0.404	2.1818 (0.3748, 12.7011) /0.385	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.494
35 - <50	3/162 (2%)	2/132 (2%)	1.2264 (0.2019, 7.4501) /0.825	0.3367 (-2.6048, 3.2782) /0.822	1.2222 (0.2073, 7.2069) /0.825	
>=50	2/ 66 (3%)	3/ 96 (3%)	0.9688 (0.1574, 5.9628) /0.973	-0.0947 (-5.5000, 5.3106) /0.973	0.9697 (0.1666, 5.6449) /0.973	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	0.288
35 - <50	3/162 (2%)	2/132 (2%)	1.2264 (0.2019, 7.4501) /0.825	0.3367 (-2.6048, 3.2782) /0.822	1.2222 (0.2073, 7.2069) /0.825	
>=50	1/ 66 (2%)	2/ 96 (2%)	0.7231 (0.0642, 8.1413) /0.793	-0.5682 (-4.6728, 3.5364) /0.786	0.7273 (0.0673, 7.8574) /0.793	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	0.364
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	1/ 96 (1%)	2.9687 (0.2636, 33.4293) /0.378	1.9886 (-2.6187, 6.5960) /0.398	2.9091 (0.2693, 31.4296) /0.379	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation <35	0/ 80	0/ 80	NC	NC	NC	0.997
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	2/ 66 (3%)	2/ 96 (2%)	1.4687 (0.2017, 10.6968) /0.704	0.9470 (-4.0796, 5.9735) /0.712	1.4545 (0.2101, 10.0688) /0.704	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.125
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	0.550
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	1/ 96 (1%)	2.9687 (0.2636, 33.4293) /0.378	1.9886 (-2.6187, 6.5960) /0.398	2.9091 (0.2693, 31.4296) /0.379	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	0.219
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	2/ 96 (2%)	0.7231 (0.0642, 8.1413) /0.793	-0.5682 (-4.6728, 3.5364) /0.786	0.7273 (0.0673, 7.8574) /0.793	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis <35	0/ 80	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.391
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	3/ 66 (5%)	0/ 96	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
<35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Gastritis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Inguinal hernia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Abdominal pain upper						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aphthous ulcer						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental caries						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal distension						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal hernia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal pruritus						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal skin tags						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal discomfort						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Chronic gastritis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Dysphagia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilic oesophagitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epigastric discomfort						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Functional gastrointestinal disorder						
<35	0 / 80	1 / 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0 / 66	0 / 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival disorder						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids thrombosed						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritable bowel syndrome						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip dry <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Lip swelling <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mouth ulceration						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral pain <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Pancreatitis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis acute						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis chronic						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis ulcerative						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Rectal haemorrhage						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Steatorrhoea						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Tongue ulceration						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth impacted						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Umbilical hernia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	11/ 80 (14%)	7/ 80 (9%)	1.6625 (0.6097, 4.5334) /0.321	5.0000 (-4.7615, 14.7615) /0.315	1.5714 (0.6418, 3.8478) /0.323	0.450
35 - <50	42/162 (26%)	17/132 (13%)	2.3676 (1.2753, 4.3958) /0.006	13.0471 (4.2045, 21.8897) /0.004	2.0131 (1.2035, 3.3672) /0.008	
>=50	16/ 66 (24%)	19/ 96 (20%)	1.2968 (0.6099, 2.7573) /0.499	4.4508 (-8.6036, 17.5051) /0.504	1.2249 (0.6813, 2.2021) /0.498	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain <35	6/ 80 (8%)	3/ 80 (4%)	2.0811 (0.5019, 8.6282) /0.312	3.7500 (-3.3665, 10.8665) /0.302	2.0000 (0.5181, 7.7211) /0.315	0.868
35 - <50	12/162 (7%)	4/132 (3%)	2.5600 (0.8058, 8.1328) /0.111	4.3771 (-0.6044, 9.3586) /0.085	2.4444 (0.8072, 7.4025) /0.114	
>=50	3/ 66 (5%)	3/ 96 (3%)	1.4762 (0.2887, 7.5490) /0.640	1.4205 (-4.6925, 7.5334) /0.649	1.4545 (0.3028, 6.9867) /0.640	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
<35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.641
35 - <50	2/162 (1%)	3/132 (2%)	0.5375 (0.0885, 3.2652) /0.500	-1.0382 (-4.0968, 2.0205) /0.506	0.5432 (0.0921, 3.2031) /0.500	
>=50	3/ 66 (5%)	3/ 96 (3%)	1.4762 (0.2887, 7.5490) /0.640	1.4205 (-4.6925, 7.5334) /0.649	1.4545 (0.3028, 6.9867) /0.640	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.510
35 - <50	4/162 (2%)	4/132 (3%)	0.8101 (0.1987, 3.3029) /0.769	-0.5612 (-4.3377, 3.2153) /0.771	0.8148 (0.2077, 3.1961) /0.769	
>=50	1/ 66 (2%)	4/ 96 (4%)	0.3538 (0.0387, 3.2391) /0.358	-2.6515 (-7.6177, 2.3147) /0.295	0.3636 (0.0416, 3.1809) /0.361	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity <35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.729
35 - <50	3/162 (2%)	4/132 (3%)	0.6038 (0.1327, 2.7466) /0.514	-1.1785 (-4.7647, 2.4078) /0.520	0.6111 (0.1392, 2.6824) /0.514	
>=50	2/ 66 (3%)	2/ 96 (2%)	1.4687 (0.2017, 10.6968) /0.704	0.9470 (-4.0796, 5.9735) /0.712	1.4545 (0.2101, 10.0688) /0.704	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia <35	3/ 80 (4%)	1/ 80 (1%)	3.0779 (0.3133, 30.2376) /0.335	2.5000 (-2.3227, 7.3227) /0.310	3.0000 (0.3188, 28.2323) /0.337	0.243
35 - <50	4/162 (2%)	2/132 (2%)	1.6456 (0.2967, 9.1272) /0.569	0.9540 (-2.2167, 4.1246) /0.555	1.6296 (0.3032, 8.7592) /0.569	
>=50	3/ 66 (5%)	0/ 96	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	2/ 66 (3%)	2/ 96 (2%)	1.4687 (0.2017, 10.6968) /0.704	0.9470 (-4.0796, 5.9735) /0.712	1.4545 (0.2101, 10.0688) /0.704	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteoarthritis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	2/ 66 (3%)	2/ 96 (2%)	1.4687 (0.2017, 10.6968) /0.704	0.9470 (-4.0796, 5.9735) /0.712	1.4545 (0.2101, 10.0688) /0.704	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint swelling						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal pain <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropathy <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bursitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Foot deformity						
<35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc protrusion						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteopenia						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	
Arthritis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Costochondritis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dupuytren's contracture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Exostosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flank pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint effusion						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle tightness						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myositis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Osteonecrosi s						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Patellofemoral pain syndrome						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Polyarthriti s						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhabdomyolysis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Scoliosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal osteoarthritis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovial cyst						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temporomandibular joint syndrome						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tenosynovitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
<35	12/ 80 (15%)	11/ 80 (14%)	1.1070 (0.4573, 2.6795) /0.822	1.2500 (-9.6206, 12.1206) /0.822	1.0909 (0.5116, 2.3261) /0.822	0.134
35 - <50	42/162 (26%)	13/132 (10%)	3.2038 (1.6366, 6.2721) /<.001	16.0774 (7.6289, 24.5259) /<.001	2.6325 (1.4768, 4.6926) /0.001	
>=50	10/ 66 (15%)	11/ 96 (11%)	1.3799 (0.5497, 3.4639) /0.493	3.6932 (-7.0503, 14.4367) /0.500	1.3223 (0.5960, 2.9339) /0.492	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache <35	5/ 80 (6%)	8/ 80 (10%)	0.6000 (0.1875, 1.9201) /0.389	-3.7500 (-12.1970, 4.6970) /0.384	0.6250 (0.2136, 1.8285) /0.391	0.032
35 - <50	28/162 (17%)	7/132 (5%)	3.7313 (1.5737, 8.8474) /0.003	11.9809 (5.0156, 18.9462) /<.001	3.2593 (1.4708, 7.2226) /0.004	
>=50	1/ 66 (2%)	2/ 96 (2%)	0.7231 (0.0642, 8.1413) /0.793	-0.5682 (-4.6728, 3.5364) /0.786	0.7273 (0.0673, 7.8574) /0.793	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness <35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.092
35 - <50	2/162 (1%)	3/132 (2%)	0.5375 (0.0885, 3.2652) /0.500	-1.0382 (-4.0968, 2.0205) /0.506	0.5432 (0.0921, 3.2031) /0.500	
>=50	4/ 66 (6%)	2/ 96 (2%)	3.0323 (0.5390, 17.0595) /0.208	3.9773 (-2.4492, 10.4038) /0.225	2.9091 (0.5486, 15.4257) /0.210	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.447
35 - <50	4/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	1/ 96 (1%)	2.9687 (0.2636, 33.4293) /0.378	1.9886 (-2.6187, 6.5960) /0.398	2.9091 (0.2693, 31.4296) /0.379	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia <35	3/ 80 (4%)	1/ 80 (1%)	3.0779 (0.3133, 30.2376) /0.335	2.5000 (-2.3227, 7.3227) /0.310	3.0000 (0.3188, 28.2323) /0.337	0.279
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervicobrachial syndrome						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuralgia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Syncope						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia ^a						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Somnolence <35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anterograde amnesia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Autonomic nervous system imbalance						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Burning sensation						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebral cyst						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebrovascular accident						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cognitive disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Disturbance in attention						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysaesthesia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Dysgeusia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dystonia						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Essential tremor						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Facial paralysis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intercostal neuralgia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Loss of consciousness						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Memory impairment						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contractions involuntary						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuromuscular blockade						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post herpetic neuralgia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post-traumatic headache						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Seizure						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension headache						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	11/ 80 (14%)	16/ 80 (20%)	0.6377 (0.2754, 1.4766) /0.294	-6.2500 (-17.8161, 5.3161) /0.290	0.6875 (0.3406, 1.3877) /0.296	0.338
35 - <50	16/162 (10%)	9/132 (7%)	1.4977 (0.6394, 3.5082) /0.352	3.0584 (-3.2342, 9.3509) /0.341	1.4486 (0.6616, 3.1715) /0.354	
>=50	9/ 66 (14%)	11/ 96 (11%)	1.2201 (0.4753, 3.1318) /0.679	2.1780 (-8.2691, 12.6252) /0.683	1.1901 (0.5224, 2.7110) /0.679	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough <35	4/ 80 (5%)	3/ 80 (4%)	1.3509 (0.2925, 6.2393) /0.700	1.2500 (-5.0856, 7.5856) /0.699	1.3333 (0.3083, 5.7673) /0.700	0.924
35 - <50	8/162 (5%)	5/132 (4%)	1.3195 (0.4212, 4.1331) /0.634	1.1504 (-3.5120, 5.8128) /0.629	1.3037 (0.4368, 3.8910) /0.635	
>=50	4/ 66 (6%)	6/ 96 (6%)	0.9677 (0.2622, 3.5718) /0.961	-0.1894 (-7.7116, 7.3328) /0.961	0.9697 (0.2847, 3.3034) /0.961	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
<35	4/ 80 (5%)	8/ 80 (10%)	0.4737 (0.1367, 1.6414) /0.239	-5.0000 (-13.1256, 3.1256) /0.228	0.5000 (0.1568, 1.5942) /0.241	0.190
35 - <50	2/162 (1%)	2/132 (2%)	0.8125 (0.1129, 5.8471) /0.837	-0.2806 (-2.9702, 2.4090) /0.838	0.8148 (0.1163, 5.7067) /0.837	
>=50	3/ 66 (5%)	1/ 96 (1%)	4.5238 (0.4602, 44.4703) /0.196	3.5038 (-1.9164, 8.9240) /0.205	4.3636 (0.4639, 41.0452) /0.198	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
<35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.472
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus congestion						
<35	0/ 80	0/ 80	NC	NC	NC	0.960
35 - <50	3/162 (2%)	1/132 (<1%)	2.4717 (0.2541, 24.0434) /0.436	1.0943 (-1.4548, 3.6434) /0.400	2.4444 (0.2573, 23.2264) /0.437	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory disorder						
<35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.299
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.267
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphonia <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract congestion						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspnoea <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Productive cough						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract congestion						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchospasm <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Emphysema <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lung disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal obstruction						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal septum deviation						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pulmonary mass						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Reflux laryngitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Respiratory distress						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus pain						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Sleep apnoea syndrome						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wheezing <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	11/ 80 (14%)	6/ 80 (8%)	1.9662 (0.6898, 5.6041) /0.206	6.2500 (-3.2505, 15.7505) /0.197	1.8333 (0.7124, 4.7178) /0.209	<.001
35 - <50	24/162 (15%)	9/132 (7%)	2.3768 (1.0640, 5.3094) /0.035	7.9966 (1.0386, 14.9547) /0.024	2.1728 (1.0463, 4.5124) /0.037	
>=50	2/ 66 (3%)	16/ 96 (17%)	0.1563 (0.0346, 0.7047) /0.016	-13.6364 (-22.1616, -5.1111) /0.002	0.1818 (0.0432, 0.7645) /0.020	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
<35	2/ 80 (3%)	1/ 80 (1%)	2.0256 (0.1800, 22.7973) /0.568	1.2500 (-2.9490, 5.4490) /0.560	2.0000 (0.1850, 21.6178) /0.568	0.404
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
<35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	0.230
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	3/ 96 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-30.1817, 19.4415) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	2/132 (2%)	1.2264 (0.2019, 7.4501) /0.825	0.3367 (-2.6048, 3.2782) /0.822	1.2222 (0.2073, 7.2069) /0.825	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	0.160
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Procedural pain						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epicondylitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exposure to communicable disease						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Road traffic accident						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bone contusion						
<35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection related reaction						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Radius fracture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Soft tissue injury						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	
Upper limb fracture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Buttock injury						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Eye injury						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Facial bones fracture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Humerus fracture						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury corneal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Joint dislocation						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament rupture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Meniscus injury						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural complication						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Skin abrasion						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin injury						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Splinter						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon rupture						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth fracture						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	7/ 80 (9%)	4/ 80 (5%)	1.8219 (0.5118, 6.4861) /0.354	3.7500 (-4.0697, 11.5697) /0.347	1.7500 (0.5331, 5.7452) /0.356	0.967
35 - <50	20/162 (12%)	11/132 (8%)	1.5493 (0.7140, 3.3617) /0.268	4.0123 (-2.9080, 10.9327) /0.256	1.4815 (0.7365, 2.9801) /0.270	
>=50	9/ 66 (14%)	8/ 96 (8%)	1.7368 (0.6332, 4.7639) /0.284	5.3030 (-4.6525, 15.2586) /0.296	1.6364 (0.6657, 4.0221) /0.283	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.146
35 - <50	2/162 (1%)	2/132 (2%)	0.8125 (0.1129, 5.8471) /0.837	-0.2806 (-2.9702, 2.4090) /0.838	0.8148 (0.1163, 5.7067) /0.837	
>=50	1/ 66 (2%)	2/ 96 (2%)	0.7231 (0.0642, 8.1413) /0.793	-0.5682 (-4.6728, 3.5364) /0.786	0.7273 (0.0673, 7.8574) /0.793	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
<35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.166
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.161
35 - <50	5/162 (3%)	1/132 (<1%)	4.1720 (0.4814, 36.1585) /0.195	2.3288 (-0.7176, 5.3753) /0.134	4.0741 (0.4819, 34.4442) /0.197	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood pressure increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	3/132 (2%)	<0.0001 (<0.0001, -) />0.999	-4.5427 (-20.7046, 11.6192) /0.582	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine decreased						
<35	0/ 80	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood phosphorus decreased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Activated partial thromboplast in time prolonged						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
ECG signs of ventricular hypertrophy						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glycosylated haemoglobin increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic enzyme increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipids increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neisseria test positive						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatic enzymes increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thyroxine free decreased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<35	11/ 80 (14%)	2/ 80 (3%)	6.2174 (1.3315, 29.0324) /0.020	11.2500 (2.9644, 19.5356) /0.008	5.5000 (1.2590, 24.0268) /0.023	0.079
35 - <50	15/162 (9%)	12/132 (9%)	1.0204 (0.4601, 2.2630) /0.960	0.1684 (-6.4630, 6.7997) /0.960	1.0185 (0.4941, 2.0997) /0.960	
>=50	10/ 66 (15%)	8/ 96 (8%)	1.9643 (0.7312, 5.2770) /0.181	6.8182 (-3.4479, 17.0843) /0.193	1.8182 (0.7577, 4.3628) /0.181	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.083
35 - <50	3/162 (2%)	3/132 (2%)	0.8113 (0.1610, 4.0877) /0.800	-0.4209 (-3.7032, 2.8615) /0.802	0.8148 (0.1672, 3.9706) /0.800	
>=50	5/ 66 (8%)	1/ 96 (1%)	7.7869 (0.8882, 68.2667) /0.064	6.5341 (-0.1650, 13.2332) /0.056	7.2727 (0.8694, 60.8352) /0.067	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	0.137
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	3/ 66 (5%)	1/ 96 (1%)	4.5238 (0.4602, 44.4703) /0.196	3.5038 (-1.9164, 8.9240) /0.205	4.3636 (0.4639, 41.0452) /0.198	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema <35	4/ 80 (5%)	1/ 80 (1%)	4.1579 (0.4544, 38.0472) /0.207	3.7500 (-1.6106, 9.1106) /0.170	4.0000 (0.4570, 35.0080) /0.210	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acne <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash pruritic						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alopecia <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash generalised						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoeic dermatitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ecchymosis <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urticaria						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decubitus ulcer						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis acneiform						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis contact						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intertrigo						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Nail bed bleeding						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neurodermatitis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Onychoclasia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Photosensitivity reaction						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Purpura						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash erythematous						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash maculo-papular						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sebacous hyperplasia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoea <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin fissures						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin lesion						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Skin mass						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stasis dermatitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<35	11/ 80 (14%)	7/ 80 (9%)	1.6625 (0.6097, 4.5334) /0.321	5.0000 (-4.7615, 14.7615) /0.315	1.5714 (0.6418, 3.8478) /0.323	0.857
35 - <50	17/162 (10%)	12/132 (9%)	1.1724 (0.5388, 2.5513) /0.688	1.4029 (-5.4032, 8.2091) /0.686	1.1543 (0.5719, 2.3300) /0.689	
>=50	4/ 66 (6%)	5/ 96 (5%)	1.1742 (0.3032, 4.5467) /0.816	0.8523 (-6.4205, 8.1250) /0.818	1.1636 (0.3245, 4.1722) /0.816	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia <35	5/ 80 (6%)	2/ 80 (3%)	2.6000 (0.4894, 13.8141) /0.262	3.7500 (-2.5619, 10.0619) /0.244	2.5000 (0.4996, 12.5105) /0.265	0.746
35 - <50	8/162 (5%)	1/132 (<1%)	6.8052 (0.8401, 55.1223) /0.072	4.1807 (0.5311, 7.8303) /0.025	6.5185 (0.8257, 51.4577) /0.075	
>=50	2/ 66 (3%)	1/ 96 (1%)	2.9687 (0.2636, 33.4293) /0.378	1.9886 (-2.6187, 6.5960) /0.398	2.9091 (0.2693, 31.4296) /0.379	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety <35	2/ 80 (3%)	3/ 80 (4%)	0.6581 (0.1070, 4.0484) /0.652	-1.2500 (-6.6385, 4.1385) /0.649	0.6667 (0.1145, 3.8833) /0.652	0.366
35 - <50	5/162 (3%)	4/132 (3%)	1.0191 (0.2681, 3.8739) /0.978	0.0561 (-3.8992, 4.0114) /0.978	1.0185 (0.2791, 3.7169) /0.978	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	0.038
35 - <50	1/162 (<1%)	3/132 (2%)	0.2671 (0.0275, 2.5981) /0.255	-1.6554 (-4.4694, 1.1585) /0.249	0.2716 (0.0286, 2.5807) /0.257	
>=50	0/ 66	3/ 96 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-30.1817, 19.4415) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	2/132 (2%)	0.8125 (0.1129, 5.8471) /0.837	-0.2806 (-2.9702, 2.4090) /0.838	0.8148 (0.1163, 5.7067) /0.837	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
<35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	0.197
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
<35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse <35	2/ 80 (3%)	1/ 80 (1%)	2.0256 (0.1800, 22.7973) /0.568	1.2500 (-2.9490, 5.4490) /0.560	2.0000 (0.1850, 21.6178) /0.568	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute stress disorder						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Affect lability						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depression suicidal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Drug dependence						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritability						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Mood altered						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mood swings						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Panic disorder						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal behaviour						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Thinking abnormal						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
(Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Preferred Term						

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
<35	4/ 80 (5%)	6/ 80 (8%)	0.6491 (0.1760, 2.3938) /0.516	-2.5000 (-9.9914, 4.9914) /0.513	0.6667 (0.1955, 2.2731) /0.517	0.721
35 - <50	7/162 (4%)	9/132 (7%)	0.6172 (0.2235, 1.7043) /0.352	-2.4972 (-7.8163, 2.8219) /0.357	0.6337 (0.2425, 1.6562) /0.352	
>=50	3/ 66 (5%)	12/ 96 (13%)	0.3333 (0.0902, 1.2313) /0.099	-7.9545 (-16.2624, 0.3533) /0.061	0.3636 (0.1067, 1.2388) /0.106	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
<35	3/ 80 (4%)	5/ 80 (6%)	0.5844 (0.1349, 2.5323) /0.473	-2.5000 (-9.2429, 4.2429) /0.467	0.6000 (0.1483, 2.4268) /0.474	0.391
35 - <50	4/162 (2%)	2/132 (2%)	1.6456 (0.2967, 9.1272) /0.569	0.9540 (-2.2167, 4.1246) /0.555	1.6296 (0.3032, 8.7592) /0.569	
>=50	1/ 66 (2%)	5/ 96 (5%)	0.2800 (0.0320, 2.4535) /0.250	-3.6932 (-9.0262, 1.6398) /0.175	0.2909 (0.0348, 2.4334) /0.255	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	3/ 96 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-30.1817, 19.4415) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Decreased appetite						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	
Dehydration						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gout						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperglycaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertriglyceridaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphat aemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Increased appetite						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetes mellitus						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetic ketoacidosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Hypokalaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impaired fasting glucose						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B12 deficiency						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B6 deficiency						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<35	2/ 80 (3%)	1/ 80 (1%)	2.0256 (0.1800, 22.7973) /0.568	1.2500 (-2.9490, 5.4490) /0.560	2.0000 (0.1850, 21.6178) /0.568	0.989
35 - <50	9/162 (6%)	3/132 (2%)	2.5294 (0.6707, 9.5397) /0.171	3.2828 (-1.0652, 7.6309) /0.139	2.4444 (0.6754, 8.8471) /0.173	
>=50	5/ 66 (8%)	3/ 96 (3%)	2.5410 (0.5858, 11.0219) /0.213	4.4508 (-2.8202, 11.7218) /0.230	2.4242 (0.5998, 9.7976) /0.214	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign prostatic hyperplasia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Menorrhagia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	
Balanoposthitis						
<35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysmenorrhoe						
^a						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Adenomyosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Breast cyst						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Breast pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysfunctional uterine bleeding						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital erythema						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menometrorrhagia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Menstrual disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metrorrhagia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst ruptured						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Penile pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	
<hr/>						
Scrotal mass						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal discharge						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal haemorrhage						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.872
35 - <50	7/162 (4%)	7/132 (5%)	0.8065 (0.2756, 2.3601) /0.695	-0.9820 (-5.9235, 3.9594) /0.697	0.8148 (0.2932, 2.2645) /0.695	
>=50	1/ 66 (2%)	3/ 96 (3%)	0.4769 (0.0485, 4.6873) /0.525	-1.6098 (-6.1705, 2.9508) /0.489	0.4848 (0.0515, 4.5606) /0.527	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	4/162 (2%)	3/132 (2%)	1.0886 (0.2393, 4.9521) /0.913	0.1964 (-3.2927, 3.6856) /0.912	1.0864 (0.2475, 4.7688) /0.913	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia folate deficiency						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Deficiency anaemia						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Eosinophilia						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Leukocytosis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
<hr/>						
Microcytic anaemia <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neutropenia <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thrombocytopenia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.112
35 - <50	10/162 (6%)	2/132 (2%)	4.2763 (0.9203, 19.8702) /0.064	4.6577 (0.4060, 8.9093) /0.032	4.0741 (0.9084, 18.2713) /0.067	
>=50	2/ 66 (3%)	5/ 96 (5%)	0.5688 (0.1070, 3.0234) /0.508	-2.1780 (-8.2492, 3.8931) /0.482	0.5818 (0.1163, 2.9096) /0.510	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension <35	0/ 80	0/ 80	NC	NC	NC	0.620
35 - <50	7/162 (4%)	1/132 (<1%)	5.9161 (0.7186, 48.7080) /0.098	3.5634 (0.1005, 7.0263) /0.044	5.7037 (0.7107, 45.7762) /0.101	
>=50	2/ 66 (3%)	2/ 96 (2%)	1.4687 (0.2017, 10.6968) /0.704	0.9470 (-4.0796, 5.9735) /0.712	1.4545 (0.2101, 10.0688) /0.704	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deep vein thrombosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertensive crisis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Orthostatic hypotension						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Phlebitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicophlebitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicose vein						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Venous thrombosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
<35	3/ 80 (4%)	1/ 80 (1%)	3.0779 (0.3133, 30.2376) /0.335	2.5000 (-2.3227, 7.3227) /0.310	3.0000 (0.3188, 28.2323) /0.337	0.006
35 - <50	8/162 (5%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	5/ 96 (5%)	0.2800 (0.0320, 2.4535) /0.250	-3.6932 (-9.0262, 1.6398) /0.175	0.2909 (0.0348, 2.4334) /0.255	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal colic						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal impairment						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic kidney disease						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Micturition urgency						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral discharge						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
<35	0/ 80	4/ 80 (5%)	<0.0001 (<0.0001, -) />0.999	-7.1707 (-30.0734, 15.7321) /0.539	<0.0001 (<0.0001, -) />0.999	0.019
35 - <50	5/162 (3%)	1/132 (<1%)	4.1720 (0.4814, 36.1585) /0.195	2.3288 (-0.7176, 5.3753) /0.134	4.0741 (0.4819, 34.4442) /0.197	
>=50	2/ 66 (3%)	5/ 96 (5%)	0.5688 (0.1070, 3.0234) /0.508	-2.1780 (-8.2492, 3.8931) /0.482	0.5818 (0.1163, 2.9096) /0.510	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis allergic						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pruritus <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid oedema						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vision blurred						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Cataract <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract subcapsular						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctival haemorrhage						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry eye						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Eye pain						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye swelling						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Lacrimation increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ocular hyperaemia						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous haematoma						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	2/ 80 (3%)	2/ 80 (3%)	1.0000 (0.1374, 7.2786) />0.999	<0.0001 (-4.8383, 4.8383) />0.999	1.0000 (0.1444, 6.9262) />0.999	0.815
35 - <50	6/162 (4%)	3/132 (2%)	1.6538 (0.4056, 6.7430) /0.483	1.4310 (-2.4318, 5.2937) /0.468	1.6296 (0.4155, 6.3921) /0.484	
>=50	1/ 66 (2%)	2/ 96 (2%)	0.7231 (0.0642, 8.1413) /0.793	-0.5682 (-4.6728, 3.5364) /0.786	0.7273 (0.0673, 7.8574) /0.793	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anogenital warts						
<35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	0.993
35 - <50	3/162 (2%)	2/132 (2%)	1.2264 (0.2019, 7.4501) /0.825	0.3367 (-2.6048, 3.2782) /0.822	1.2222 (0.2073, 7.2069) /0.825	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Basal cell carcinoma						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fibrous histiocytoma						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Knuckle pads						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Melanocytic naevus						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papillary thyroid cancer						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seminoma						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin papilloma						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Squamous cell carcinoma						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Squamous cell carcinoma of skin						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	2/132 (2%)	1.2264 (0.2019, 7.4501) /0.825	0.3367 (-2.6048, 3.2782) /0.822	1.2222 (0.2073, 7.2069) /0.825	
>=50	4/ 66 (6%)	0/ 96	>999 (>999, >999) /NC	8.1845 (-13.2031, 29.5721) /0.453	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deafness						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear discomfort						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Ear pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Excessive cerumen production						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
<35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.068
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
<35	0/ 80	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Allergy to animal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug hypersensitivity						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycotic allergy						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	4/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bradycardia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Cardiovascular disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Palpitations						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Sinus tachycardia						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ventricular extrasystoles						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Endocrine disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidism						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypogonadism						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Thyroid mass						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Biliary tract disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis acute						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Hyperbilirubinaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion missed						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion spontaneous						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Social circumstances						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menopause						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Stress at work						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental implantation						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	91/ 99 (92%)	72/104 (69%)	5.0556 (2.1954, 11.6421) /<.001	22.6884 (12.3200, 33.0569) /<.001	1.3277 (1.1533, 1.5285) /<.001	0.922
Male	203/209 (97%)	148/204 (73%)	12.8018 (5.3732, 30.5009) /<.001	24.5802 (18.0512, 31.1091) /<.001	1.3388 (1.2266, 1.4613) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
Female	51/ 99 (52%)	50/104 (48%)	1.1475 (0.6616, 1.9904) /0.624	3.4382 (-10.3140, 17.1905) /0.624	1.0715 (0.8127, 1.4127) /0.624	0.546
Male	138/209 (66%)	114/204 (56%)	1.5345 (1.0308, 2.2843) /0.035	10.1464 (0.7840, 19.5087) /0.034	1.1816 (1.0109, 1.3810) /0.036	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
Female	11/ 99 (11%)	7/104 (7%)	1.7321 (0.6432, 4.6643) /0.277	4.3803 (-3.4626, 12.2233) /0.274	1.6508 (0.6666, 4.0880) /0.279	0.465
Male	41/209 (20%)	35/204 (17%)	1.1784 (0.7154, 1.9410) /0.519	2.4604 (-5.0061, 9.9268) /0.518	1.1434 (0.7605, 1.7190) /0.519	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
Female	8/ 99 (8%)	10/104 (10%)	0.8264 (0.3122, 2.1872) /0.701	-1.5346 (-9.3399, 6.2708) /0.700	0.8404 (0.3458, 2.0425) /0.701	0.258
Male	24/209 (11%)	15/204 (7%)	1.6346 (0.8313, 3.2143) /0.154	4.1303 (-1.4831, 9.7438) /0.149	1.5617 (0.8438, 2.8903) /0.156	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza Female	7/ 99 (7%)	5/104 (5%)	1.5065 (0.4619, 4.9136) /0.497	2.2630 (-4.2486, 8.7746) /0.496	1.4707 (0.4827, 4.4812) /0.497	0.673
Male	10/209 (5%)	9/204 (4%)	1.0888 (0.4331, 2.7374) /0.857	0.3729 (-3.6662, 4.4121) /0.856	1.0845 (0.4500, 2.6137) /0.857	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
Female	1/ 99 (1%)	5/104 (5%)	0.2020 (0.0232, 1.7609) /0.148	-3.7976 (-8.3566, 0.7614) /0.103	0.2101 (0.0250, 1.7668) /0.151	0.199
Male	10/209 (5%)	12/204 (6%)	0.8040 (0.3394, 1.9044) /0.620	-1.0977 (-5.4334, 3.2381) /0.620	0.8134 (0.3594, 1.8408) /0.620	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis Female	5/ 99 (5%)	3/104 (3%)	1.7908 (0.4164, 7.7007) /0.434	2.1659 (-3.2151, 7.5469) /0.430	1.7508 (0.4297, 7.1331) /0.434	0.409
Male	8/209 (4%)	9/204 (4%)	0.8624 (0.3261, 2.2806) /0.765	-0.5840 (-4.4190, 3.2510) /0.765	0.8676 (0.3414, 2.2048) /0.765	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
Female	3/ 99 (3%)	4/104 (4%)	0.7813 (0.1704, 3.5825) /0.751	-0.8159 (-5.8221, 4.1904) /0.749	0.7879 (0.1809, 3.4316) /0.751	0.929
Male	7/209 (3%)	8/204 (4%)	0.8490 (0.3021, 2.3858) /0.756	-0.5723 (-4.1841, 3.0395) /0.756	0.8541 (0.3155, 2.3120) /0.756	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis Female	2/ 99 (2%)	5/104 (5%)	0.4082 (0.0773, 2.1548) /0.291	-2.7875 (-7.7458, 2.1708) /0.271	0.4202 (0.0834, 2.1160) /0.293	0.478
Male	6/209 (3%)	7/204 (3%)	0.8318 (0.2747, 2.5187) /0.745	-0.5606 (-3.9317, 2.8106) /0.744	0.8366 (0.2860, 2.4470) /0.745	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
Female	6/ 99 (6%)	5/104 (5%)	1.2774 (0.3771, 4.3273) /0.694	1.2529 (-4.9918, 7.4976) /0.694	1.2606 (0.3974, 3.9991) /0.694	0.784
Male	5/209 (2%)	3/204 (1%)	1.6422 (0.3873, 6.9626) /0.501	0.9218 (-1.7279, 3.5714) /0.495	1.6268 (0.3939, 6.7188) /0.501	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
Female	0/ 99	4/104 (4%)	<0.0001 (<0.0001, -) />0.999	-6.0646 (-26.5588, 14.4297) /0.562	<0.0001 (<0.0001, -) />0.999	0.051
Male	5/209 (2%)	6/204 (3%)	0.8088 (0.2429, 2.6930) /0.730	-0.5488 (-3.6581, 2.5604) /0.729	0.8134 (0.2522, 2.6235) /0.730	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis Female	3/ 99 (3%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Male	5/209 (2%)	5/204 (2%)	0.9755 (0.2781, 3.4214) /0.969	-0.0586 (-3.0241, 2.9069) /0.969	0.9761 (0.2869, 3.3210) /0.969	
Syphilis Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	4/209 (2%)	9/204 (4%)	0.4228 (0.1281, 1.3952) /0.158	-2.4979 (-5.8730, 0.8772) /0.147	0.4338 (0.1357, 1.3864) /0.159	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.623
Male	7/209 (3%)	3/204 (1%)	2.3218 (0.5920, 9.1053) /0.227	1.8787 (-1.0672, 4.8246) /0.211	2.2775 (0.5971, 8.6864) /0.228	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
Female	4/ 99 (4%)	3/104 (3%)	1.4175 (0.3091, 6.5004) /0.653	1.1558 (-3.8833, 6.1948) /0.653	1.4007 (0.3216, 6.1006) /0.654	0.772
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	7/209 (3%)	3/204 (1%)	2.3218 (0.5920, 9.1053) /0.227	1.8787 (-1.0672, 4.8246) /0.211	2.2775 (0.5971, 8.6864) /0.228	
Gonorrhoea						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	6/209 (3%)	4/204 (2%)	1.4778 (0.4108, 5.3159) /0.550	0.9100 (-2.0472, 3.8672) /0.546	1.4641 (0.4193, 5.1121) /0.550	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes						
Female	2/ 99 (2%)	2/104 (2%)	1.0515 (0.1452, 7.6129) /0.960	0.0971 (-3.7300, 3.9243) /0.960	1.0505 (0.1509, 7.3142) /0.960	0.954
Male	3/209 (1%)	3/204 (1%)	0.9757 (0.1946, 4.8914) /0.976	-0.0352 (-2.3436, 2.2733) /0.976	0.9761 (0.1993, 4.7799) /0.976	
Herpes zoster						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.607
Male	5/209 (2%)	2/204 (<1%)	2.4755 (0.4748, 12.9069) /0.282	1.4120 (-1.0619, 3.8858) /0.263	2.4402 (0.4789, 12.4350) /0.283	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis						
Female	1/ 99 (1%)	3/104 (3%)	0.3435 (0.0351, 3.3592) /0.358	-1.8745 (-5.6464, 1.8974) /0.330	0.3502 (0.0370, 3.3103) /0.360	0.307
Male	3/209 (1%)	2/204 (<1%)	1.4709 (0.2432, 8.8955) /0.674	0.4550 (-1.6494, 2.5594) /0.672	1.4641 (0.2472, 8.6713) /0.674	
Viral upper respiratory tract infection						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	6/209 (3%)	3/204 (1%)	1.9803 (0.4885, 8.0269) /0.339	1.4002 (-1.4022, 4.2027) /0.327	1.9522 (0.4949, 7.7010) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydial infection						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	5/209 (2%)	3/204 (1%)	1.6422 (0.3873, 6.9626) /0.501	0.9218 (-1.7279, 3.5714) /0.495	1.6268 (0.3939, 6.7188) /0.501	
Gastroenteritis viral						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	5/209 (2%)	1/204 (<1%)	4.9755 (0.5762, 42.9626) /0.145	1.9021 (-0.3805, 4.1848) /0.102	4.8804 (0.5751, 41.4121) /0.146	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.516
Male	1/209 (<1%)	3/204 (1%)	0.3221 (0.0332, 3.1224) /0.328	-0.9921 (-2.8905, 0.9062) /0.306	0.3254 (0.0341, 3.1022) /0.329	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute sinusitis						
Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	0.679
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	4/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.287
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia Female	0/ 99	3/104 (3%)	<0.0001 (<0.0001, -) />0.999	-5.1377 (-25.6021, 15.3266) /0.623	<0.0001 (<0.0001, -) />0.999	0.142
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Cystitis Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	0.422
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.198
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.179
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	
Onychomycosis						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	3/204 (1%)	0.3221 (0.0332, 3.1224) /0.328	-0.9921 (-2.8905, 0.9062) /0.306	0.3254 (0.0341, 3.1022) /0.329	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Secondary syphilis						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	
Tinea versicolour						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	3/209 (1%)	1/204 (<1%)	2.9563 (0.3050, 28.6570) /0.350	0.9452 (-0.9307, 2.8211) /0.323	2.9282 (0.3071, 27.9197) /0.350	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth infection						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Acarodermatitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal chlamydia infection						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	
Candida infection						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.317
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatitis A						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
Female	3/ 99 (3%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Oropharyngeal gonococcal infection						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Proctitis gonococcal						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea cruris						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	
Tracheitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	3/204 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis gonococcal						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Vaginal infection						
Female	1/ 99 (1%)	2/104 (2%)	0.5204 (0.0464, 5.8315) /0.596	-0.9130 (-4.2064, 2.3804) /0.587	0.5253 (0.0484, 5.7016) /0.597	>0.999
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Body tinea						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic tonsillitis						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Genital herpes simplex						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impetigo						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site cellulitis						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Otitis media acute						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Pulpitis dental Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal infection						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Subcutaneous abscess						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth abscess						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Urethritis						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis chlamydial						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Viral infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Acute hepatitis B						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis C						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Amoebiasis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Angular cheilitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal human papilloma virus infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Appendicitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervicitis human papilloma virus						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Clostridium difficile colitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis bacterial						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Enteritis infectious						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Epididymitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Folliculitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastric infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastroenteritis Escherichia coli						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Gastrointestinal viral infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Groin abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes virus infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Infected bite						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Infection parasitic						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Liver abscess Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Localised infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nasal herpes						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral candidiasis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Periodontitis						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pertussis Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pneumonia mycoplasmal Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post procedural infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Primary syphilis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis chlamydial						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Proctitis herpes						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Pyelonephritis acute						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rotavirus infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted disease						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Skin candida						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal skin infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Tinea infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea pedis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tongue fungal infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureaplasma infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Viral tonsillitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal candidiasis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Vulvovaginitis trichomonal						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
Female	79/ 99 (80%)	10/104 (10%)	37.1299 (16.4202, 83.9595) /<.001	70.1826 (60.4535, 79.9116) /<.001	8.2990 (4.5659, 15.0843) /<.001	0.210
Male	173/209 (83%)	12/204 (6%)	76.8889 (38.7641, 152.5096) /<.001	76.8928 (70.8404, 82.9452) /<.001	14.0718 (8.0995, 24.4479) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
Female	68/ 99 (69%)	0/104	>999 (>999, >999) /NC	NC	NC	NC
Male	163/209 (78%)	0/204	>999 (>999, >999) /NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
Female	15/ 99 (15%)	0/104	>999 (>999, >999) /NC	16.8456 (-3.8538, 37.5449) /0.111	>999 (>999, >999) /NC	NC
Male	22/209 (11%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
Female	13/ 99 (13%)	0/104	>999 (>999, >999) /NC	14.9229 (-5.6695, 35.5153) /0.156	>999 (>999, >999) /NC	NC
Male	17/209 (8%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
Female	5/ 99 (5%)	2/104 (2%)	2.7128 (0.5140, 14.3187) /0.240	3.1274 (-1.9297, 8.1845) /0.225	2.6263 (0.5215, 13.2252) /0.242	0.861
Male	16/209 (8%)	7/204 (3%)	2.3331 (0.9390, 5.7967) /0.068	4.2241 (-0.1615, 8.6097) /0.059	2.2310 (0.9375, 5.3092) /0.070	
Fatigue						
Female	7/ 99 (7%)	2/104 (2%)	3.8804 (0.7862, 19.1534) /0.096	5.1476 (-0.5500, 10.8453) /0.077	3.6768 (0.7826, 17.2742) /0.099	0.996
Male	15/209 (7%)	4/204 (2%)	3.8660 (1.2608, 11.8543) /0.018	5.2162 (1.2332, 9.1993) /0.010	3.6603 (1.2357, 10.8425) /0.019	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
Female	9/ 99 (9%)	0/104	>999 (>999, >999) /NC	11.0748 (-9.2892, 31.4389) /0.286	>999 (>999, >999) /NC	>0.999
Male	14/209 (7%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
Female	4/ 99 (4%)	2/104 (2%)	2.1474 (0.3844, 11.9948) /0.384	2.1173 (-2.5743, 6.8089) /0.376	2.1010 (0.3936, 11.2160) /0.385	0.373
Male	7/209 (3%)	1/204 (<1%)	7.0347 (0.8577, 57.6951) /0.069	2.8591 (0.2383, 5.4799) /0.033	6.8325 (0.8482, 55.0414) /0.071	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
Female	6/ 99 (6%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	7/209 (3%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
Female	5/ 99 (5%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	5/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pain						
Female	3/ 99 (3%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.336
Male	5/209 (2%)	1/204 (<1%)	4.9755 (0.5762, 42.9626) /0.145	1.9021 (-0.3805, 4.1848) /0.102	4.8804 (0.5751, 41.4121) /0.146	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chills						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	6/209 (3%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site haematoma						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	5/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pruritus						
Female	5/ 99 (5%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Asthenia						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	4/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site warmth						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	5/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site reaction						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.971
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.317
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Cyst Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Discomfort Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Feeling hot Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oedema peripheral						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chest discomfort						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Feeling of body temperature change						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Injection site anaesthesia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discolouration						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site discomfort						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Peripheral swelling						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vessel puncture site pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	20/ 99 (20%)	13/104 (13%)	1.7722 (0.8283, 3.7914) /0.140	7.7020 (-2.4446, 17.8486) /0.137	1.6162 (0.8507, 3.0704) /0.143	0.975
Male	54/209 (26%)	33/204 (16%)	1.8053 (1.1120, 2.9308) /0.017	9.6608 (1.8664, 17.4553) /0.015	1.5972 (1.0839, 2.3537) /0.018	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
Female	6/ 99 (6%)	3/104 (3%)	2.1720 (0.5280, 8.9344) /0.282	3.1760 (-2.5195, 8.8715) /0.274	2.1010 (0.5402, 8.1721) /0.284	0.536
Male	16/209 (8%)	12/204 (6%)	1.3264 (0.6113, 2.8782) /0.475	1.7731 (-3.0662, 6.6125) /0.473	1.3014 (0.6315, 2.6823) /0.475	
Nausea						
Female	4/ 99 (4%)	3/104 (3%)	1.4175 (0.3091, 6.5004) /0.653	1.1558 (-3.8833, 6.1948) /0.653	1.4007 (0.3216, 6.1006) /0.654	0.237
Male	10/209 (5%)	2/204 (<1%)	5.0754 (1.0982, 23.4566) /0.038	3.8043 (0.6103, 6.9983) /0.020	4.8804 (1.0826, 22.0013) /0.039	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)	
Toothache	Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	0.353
	Male	3/209 (1%)	5/204 (2%)	0.5796 (0.1367, 2.4575) /0.459	-1.0156 (-3.6807, 1.6495) /0.455	0.5856 (0.1418, 2.4188) /0.460	
Vomiting	Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.783
	Male	5/209 (2%)	3/204 (1%)	1.6422 (0.3873, 6.9626) /0.501	0.9218 (-1.7279, 3.5714) /0.495	1.6268 (0.3939, 6.7188) /0.501	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	0.707
Male	4/209 (2%)	1/204 (<1%)	3.9610 (0.4389, 35.7437) /0.220	1.4237 (-0.6665, 3.5139) /0.182	3.9043 (0.4401, 34.6355) /0.221	
Constipation Female	3/ 99 (3%)	3/104 (3%)	1.0521 (0.2073, 5.3403) /0.951	0.1457 (-4.5180, 4.8093) /0.951	1.0505 (0.2171, 5.0821) /0.951	0.276
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.090
Male	5/209 (2%)	1/204 (<1%)	4.9755 (0.5762, 42.9626) /0.145	1.9021 (-0.3805, 4.1848) /0.102	4.8804 (0.5751, 41.4121) /0.146	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.110
Male	4/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Haemorrhoids						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	4/209 (2%)	2/204 (<1%)	1.9707 (0.3570, 10.8794) /0.436	0.9335 (-1.3640, 3.2310) /0.426	1.9522 (0.3615, 10.5414) /0.437	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	4/204 (2%)	0.2404 (0.0266, 2.1692) /0.204	-1.4823 (-3.6025, 0.6379) /0.171	0.2440 (0.0275, 2.1647) /0.205	
Flatulence Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Gastritis						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.317
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Abdominal pain upper						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aphthous ulcer						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Colitis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dental caries						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Enteritis						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Odynophagia						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal distension						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Abdominal hernia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal pruritus						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Anal skin tags						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal discomfort						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chronic gastritis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphagia Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Eosinophilic oesophagitis Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epigastric discomfort						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Functional gastrointestinal disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Haemorrhoids thrombosed						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritable bowel syndrome						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Lip dry						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip swelling						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Mouth ulceration						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral disorder						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Oral pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pancreatitis acute						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis chronic						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Proctitis ulcerative						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Steatorrhoea						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tongue ulceration						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Tooth impacted						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Umbilical hernia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
Female	19/ 99 (19%)	16/104 (15%)	1.3062 (0.6290, 2.7125) /0.474	3.8073 (-6.5976, 14.2122) /0.473	1.2475 (0.6809, 2.2854) /0.474	0.327
Male	50/209 (24%)	27/204 (13%)	2.0615 (1.2321, 3.4493) /0.006	10.6882 (3.2668, 18.1095) /0.005	1.8075 (1.1800, 2.7689) /0.007	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain Female	5/ 99 (5%)	3/104 (3%)	1.7908 (0.4164, 7.7007) /0.434	2.1659 (-3.2151, 7.5469) /0.430	1.7508 (0.4297, 7.1331) /0.434	0.775
Male	16/209 (8%)	7/204 (3%)	2.3331 (0.9390, 5.7967) /0.068	4.2241 (-0.1615, 8.6097) /0.059	2.2310 (0.9375, 5.3092) /0.070	
Arthralgia Female	2/ 99 (2%)	2/104 (2%)	1.0515 (0.1452, 7.6129) /0.960	0.0971 (-3.7300, 3.9243) /0.960	1.0505 (0.1509, 7.3142) /0.960	0.684
Male	4/209 (2%)	6/204 (3%)	0.6439 (0.1790, 2.3162) /0.500	-1.0273 (-3.9982, 1.9435) /0.498	0.6507 (0.1864, 2.2720) /0.501	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
Female	1/ 99 (1%)	4/104 (4%)	0.2551 (0.0280, 2.3230) /0.225	-2.8361 (-7.0241, 1.3520) /0.184	0.2626 (0.0299, 2.3093) /0.228	0.376
Male	4/209 (2%)	5/204 (2%)	0.7766 (0.2056, 2.9339) /0.709	-0.5371 (-3.3572, 2.2829) /0.709	0.7809 (0.2127, 2.8668) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
Female	3/ 99 (3%)	3/104 (3%)	1.0521 (0.2073, 5.3403) /0.951	0.1457 (-4.5180, 4.8093) /0.951	1.0505 (0.2171, 5.0821) /0.951	0.588
Male	3/209 (1%)	5/204 (2%)	0.5796 (0.1367, 2.4575) /0.459	-1.0156 (-3.6807, 1.6495) /0.455	0.5856 (0.1418, 2.4188) /0.460	
Myalgia						
Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	0.674
Male	8/209 (4%)	2/204 (<1%)	4.0199 (0.8433, 19.1634) /0.081	2.8474 (-0.0842, 5.7789) /0.057	3.9043 (0.8392, 18.1653) /0.082	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
Female	1/ 99 (1%)	3/104 (3%)	0.3435 (0.0351, 3.3592) /0.358	-1.8745 (-5.6464, 1.8974) /0.330	0.3502 (0.0370, 3.3103) /0.360	0.570
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.179
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain						
Female	3/ 99 (3%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Osteoarthritis						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.017
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	4/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Joint swelling						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.294
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Arthropathy						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bursitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Foot deformity						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intervertebral disc protrusion						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Osteopenia						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Costochondritis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dupuytren's contracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Exostosis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flank pain						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Intervertebral disc disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint effusion						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Muscle tightness						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Myositis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteonecrosis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Patellofemoral pain syndrome						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Polyarthriti						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rhabdomyolys						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scoliosis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Spinal osteoarthritis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Synovial cyst						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Temporomandibular joint syndrome						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tenosynovitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
Female	26/ 99 (26%)	13/104 (13%)	2.4932 (1.1972, 5.1918) /0.015	13.7626 (3.0135, 24.5117) /0.012	2.1010 (1.1459, 3.8522) /0.016	0.578
Male	38/209 (18%)	22/204 (11%)	1.8384 (1.0448, 3.2347) /0.035	7.3975 (0.6551, 14.1399) /0.032	1.6860 (1.0346, 2.7475) /0.036	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache Female	15/ 99 (15%)	6/104 (6%)	2.9167 (1.0831, 7.8541) /0.034	9.3823 (1.0178, 17.7468) /0.028	2.6263 (1.0615, 6.4976) /0.037	0.448
Male	19/209 (9%)	11/204 (5%)	1.7545 (0.8131, 3.7860) /0.152	3.6988 (-1.2809, 8.6784) /0.145	1.6860 (0.8230, 3.4536) /0.153	
Dizziness Female	2/ 99 (2%)	2/104 (2%)	1.0515 (0.1452, 7.6129) /0.960	0.0971 (-3.7300, 3.9243) /0.960	1.0505 (0.1509, 7.3142) /0.960	0.520
Male	7/209 (3%)	3/204 (1%)	2.3218 (0.5920, 9.1053) /0.227	1.8787 (-1.0672, 4.8246) /0.211	2.2775 (0.5971, 8.6864) /0.228	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica Female	3/ 99 (3%)	1/104 (<1%)	3.2187 (0.3292, 31.4746) /0.315	2.0688 (-1.7938, 5.9313) /0.294	3.1515 (0.3334, 29.7926) /0.317	0.226
Male	4/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Paraesthesia Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.570
Male	3/209 (1%)	1/204 (<1%)	2.9563 (0.3050, 28.6570) /0.350	0.9452 (-0.9307, 2.8211) /0.323	2.9282 (0.3071, 27.9197) /0.350	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.142
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cervicobrachial syndrome Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.047
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuralgia Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.053
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Syncope Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.053
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia ^a						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Neuropathy peripheral						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Somnolence Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anterograde amnesia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Autonomic nervous system imbalance						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Burning sensation						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Cerebral cyst						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebrovascular accident						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Cognitive disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dysaesthesia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysgeusia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Dystonia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Essential tremor						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Facial paralysis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intercostal neuralgia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Loss of consciousness						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Memory impairment						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Muscle contractions involuntary						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neuromuscular blockade						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Post herpetic neuralgia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post-traumatic headache						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Seizure						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension headache						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	16/ 99 (16%)	11/104 (11%)	1.6298 (0.7158, 3.7106) /0.245	5.5847 (-3.7701, 14.9395) /0.242	1.5280 (0.7463, 3.1287) /0.246	0.143
Male	20/209 (10%)	25/204 (12%)	0.7577 (0.4066, 1.4120) /0.382	-2.6855 (-8.6984, 3.3273) /0.381	0.7809 (0.4481, 1.3608) /0.383	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
Female	9/ 99 (9%)	7/104 (7%)	1.3857 (0.4954, 3.8758) /0.534	2.3601 (-5.0733, 9.7936) /0.534	1.3506 (0.5231, 3.4876) /0.535	0.649
Male	7/209 (3%)	7/204 (3%)	0.9752 (0.3359, 2.8315) /0.963	-0.0821 (-3.5735, 3.4093) /0.963	0.9761 (0.3486, 2.7333) /0.963	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
Female	1/ 99 (1%)	2/104 (2%)	0.5204 (0.0464, 5.8315) /0.596	-0.9130 (-4.2064, 2.3804) /0.587	0.5253 (0.0484, 5.7016) /0.597	0.696
Male	8/209 (4%)	9/204 (4%)	0.8624 (0.3261, 2.2806) /0.765	-0.5840 (-4.4190, 3.2510) /0.765	0.8676 (0.3414, 2.2048) /0.765	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal congestion						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.005
Male	0/209	4/204 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Sinus congestion						
Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	0.966
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
Female	2/ 99 (2%)	2/104 (2%)	1.0515 (0.1452, 7.6129) /0.960	0.0971 (-3.7300, 3.9243) /0.960	1.0505 (0.1509, 7.3142) /0.960	0.264
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Rhinorrhoea						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.017
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.294
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Dysphonia Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.047
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract congestion						
Female	1/ 99 (1%)	2/104 (2%)	0.5204 (0.0464, 5.8315) /0.596	-0.9130 (-4.2064, 2.3804) /0.587	0.5253 (0.0484, 5.7016) /0.597	>0.999
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Dyspnoea Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Productive cough						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract congestion						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rhinitis allergic						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchospasm Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Emphysema Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lung disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Nasal obstruction						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal septum deviation						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Pneumonitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pulmonary mass						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Reflux laryngitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory distress						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Sinus pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sleep apnoea syndrome						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Wheezing						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	8/ 99 (8%)	5/104 (5%)	1.7407 (0.5495, 5.5140) /0.346	3.2731 (-3.4890, 10.0352) /0.343	1.6808 (0.5691, 4.9640) /0.347	0.470
Male	29/209 (14%)	26/204 (13%)	1.1030 (0.6247, 1.9474) /0.735	1.1305 (-5.4198, 7.6808) /0.735	1.0887 (0.6650, 1.7824) /0.735	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament sprain						
Female	3/ 99 (3%)	1/104 (<1%)	3.2187 (0.3292, 31.4746) /0.315	2.0688 (-1.7938, 5.9313) /0.294	3.1515 (0.3334, 29.7926) /0.317	0.964
Male	3/209 (1%)	1/204 (<1%)	2.9563 (0.3050, 28.6570) /0.350	0.9452 (-0.9307, 2.8211) /0.323	2.9282 (0.3071, 27.9197) /0.350	
Muscle strain						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	3/209 (1%)	5/204 (2%)	0.5796 (0.1367, 2.4575) /0.459	-1.0156 (-3.6807, 1.6495) /0.455	0.5856 (0.1418, 2.4188) /0.460	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion						
Female	1/ 99 (1%)	2/104 (2%)	0.5204 (0.0464, 5.8315) /0.596	-0.9130 (-4.2064, 2.3804) /0.587	0.5253 (0.0484, 5.7016) /0.597	0.433
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Arthropod bite						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	3/209 (1%)	2/204 (<1%)	1.4709 (0.2432, 8.8955) /0.674	0.4550 (-1.6494, 2.5594) /0.672	1.4641 (0.2472, 8.6713) /0.674	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Procedural pain						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	3/204 (1%)	0.3221 (0.0332, 3.1224) /0.328	-0.9921 (-2.8905, 0.9062) /0.306	0.3254 (0.0341, 3.1022) /0.329	
Epicondylitis						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exposure to communicable disease						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Limb injury						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Road traffic accident						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Animal bite						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bone contusion						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Hand fracture						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection related reaction						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Radius fracture						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	>0.999
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Soft tissue injury						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Thermal burn						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Upper limb fracture						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Buttock injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Facial bones fracture						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Humerus fracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury corneal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Joint dislocation						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament rupture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Meniscus injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Post procedural complication Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Skin abrasion						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Skin injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skull fracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Splinter						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Tendon rupture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth fracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	9/ 99 (9%)	5/104 (5%)	1.9800 (0.6397, 6.1286) /0.236	4.2832 (-2.7148, 11.2813) /0.230	1.8909 (0.6564, 5.4470) /0.238	0.674
Male	27/209 (13%)	18/204 (9%)	1.5330 (0.8161, 2.8796) /0.184	4.0951 (-1.8904, 10.0807) /0.180	1.4641 (0.8327, 2.5743) /0.185	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	6/209 (3%)	4/204 (2%)	1.4778 (0.4108, 5.3159) /0.550	0.9100 (-2.0472, 3.8672) /0.546	1.4641 (0.4193, 5.1121) /0.550	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.298
Male	4/209 (2%)	3/204 (1%)	1.3073 (0.2889, 5.9151) /0.728	0.4433 (-2.0425, 2.9290) /0.727	1.3014 (0.2949, 5.7427) /0.728	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lipase increased						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.416
Male	5/209 (2%)	2/204 (<1%)	2.4755 (0.4748, 12.9069) /0.282	1.4120 (-1.0619, 3.8858) /0.263	2.4402 (0.4789, 12.4350) /0.283	
Alanine aminotransferase increased						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	4/209 (2%)	1/204 (<1%)	3.9610 (0.4389, 35.7437) /0.220	1.4237 (-0.6665, 3.5139) /0.182	3.9043 (0.4401, 34.6355) /0.221	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood pressure increased						
Female	3/ 99 (3%)	1/104 (<1%)	3.2187 (0.3292, 31.4746) /0.315	2.0688 (-1.7938, 5.9313) /0.294	3.1515 (0.3334, 29.7926) /0.317	0.127
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	3/209 (1%)	1/204 (<1%)	2.9563 (0.3050, 28.6570) /0.350	0.9452 (-0.9307, 2.8211) /0.323	2.9282 (0.3071, 27.9197) /0.350	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
Female	0/ 99	2/104 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1992 (-24.6656, 16.2672) /0.688	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body temperature increased						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine decreased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.294
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood phosphorus decreased						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Blood triglycerides increased						
Female	0/ 99	2/104 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1992 (-24.6656, 16.2672) /0.688	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Weight decreased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Activated partial thromboplastin time prolonged						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Blood bilirubin increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatinine increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Blood triglycerides						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

ECG signs of ventricular hypertrophy						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Glycosylated haemoglobin increased						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic enzyme increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Lipids increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Liver function test abnormal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Neisseria test positive						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatic enzymes increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Thyroxine free decreased						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Weight increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
Female	14/ 99 (14%)	6/104 (6%)	2.6902 (0.9902, 7.3091) /0.052	8.3722 (0.1750, 16.5693) /0.045	2.4512 (0.9808, 6.1256) /0.055	0.276
Male	22/209 (11%)	16/204 (8%)	1.3824 (0.7038, 2.7151) /0.347	2.6832 (-2.8776, 8.2439) /0.344	1.3421 (0.7260, 2.4810) /0.348	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash						
Female	4/ 99 (4%)	3/104 (3%)	1.4175 (0.3091, 6.5004) /0.653	1.1558 (-3.8833, 6.1948) /0.653	1.4007 (0.3216, 6.1006) /0.654	0.195
Male	7/209 (3%)	1/204 (<1%)	7.0347 (0.8577, 57.6951) /0.069	2.8591 (0.2383, 5.4799) /0.033	6.8325 (0.8482, 55.0414) /0.071	
Pruritus						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.336
Male	5/209 (2%)	3/204 (1%)	1.6422 (0.3873, 6.9626) /0.501	0.9218 (-1.7279, 3.5714) /0.495	1.6268 (0.3939, 6.7188) /0.501	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	4/209 (2%)	1/204 (<1%)	3.9610 (0.4389, 35.7437) /0.220	1.4237 (-0.6665, 3.5139) /0.182	3.9043 (0.4401, 34.6355) /0.221	
Acne						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash pruritic						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.971
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Alopecia						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.317
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.294
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash generalised						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.294
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Seborrhoeic dermatitis						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Ecchymosis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urticaria						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	>0.999
Male	0/209	0/204	NC	NC	NC	
Decubitus ulcer						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Dermatitis acneiform Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis contact						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Intertrigo						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nail bed bleeding						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Neurodermatitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychoclasia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Photosensitivity reaction						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Purpura						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash erythematous						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Rash maculo-papular						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sebacous hyperplasia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Seborrhoea						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin fissures						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Skin lesion						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin mass						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Stasis dermatitis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
Female	5/ 99 (5%)	7/104 (7%)	0.7371 (0.2260, 2.4040) /0.613	-1.6803 (-8.1452, 4.7847) /0.610	0.7504 (0.2463, 2.2863) /0.613	0.252
Male	27/209 (13%)	17/204 (8%)	1.6319 (0.8603, 3.0955) /0.134	4.5853 (-1.3360, 10.5066) /0.129	1.5502 (0.8720, 2.7560) /0.135	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia Female	4/ 99 (4%)	2/104 (2%)	2.1474 (0.3844, 11.9948) /0.384	2.1173 (-2.5743, 6.8089) /0.376	2.1010 (0.3936, 11.2160) /0.385	0.415
Male	11/209 (5%)	2/204 (<1%)	5.6111 (1.2280, 25.6381) /0.026	4.2828 (0.9672, 7.5983) /0.011	5.3684 (1.2048, 23.9213) /0.028	
Anxiety Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.237
Male	7/209 (3%)	7/204 (3%)	0.9752 (0.3359, 2.8315) /0.963	-0.0821 (-3.5735, 3.4093) /0.963	0.9761 (0.3486, 2.7333) /0.963	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression Female	1/ 99 (1%)	4/104 (4%)	0.2551 (0.0280, 2.3230) /0.225	-2.8361 (-7.0241, 1.3520) /0.184	0.2626 (0.0299, 2.3093) /0.228	0.364
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.142
Male	3/209 (1%)	1/204 (<1%)	2.9563 (0.3050, 28.6570) /0.350	0.9452 (-0.9307, 2.8211) /0.323	2.9282 (0.3071, 27.9197) /0.350	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.264
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	
Depressed mood						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Suicidal ideation						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute stress disorder						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Stress						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Affect lability						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anxiety disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Depression suicidal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Drug dependence						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Irritability						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mood altered						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Mood swings						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Panic disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Suicidal behaviour						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Tension						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thinking abnormal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
Female	8/ 99 (8%)	9/104 (9%)	0.9280 (0.3432, 2.5094) /0.883	-0.5730 (-8.1902, 7.0441) /0.883	0.9338 (0.3752, 2.3239) /0.883	0.103
Male	6/209 (3%)	18/204 (9%)	0.3054 (0.1187, 0.7859) /0.014	-5.9527 (-10.4554, -1.4500) /0.010	0.3254 (0.1318, 0.8031) /0.015	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
Female	6/ 99 (6%)	3/104 (3%)	2.1720 (0.5280, 8.9344) /0.282	3.1760 (-2.5195, 8.8715) /0.274	2.1010 (0.5402, 8.1721) /0.284	0.018
Male	2/209 (<1%)	9/204 (4%)	0.2093 (0.0447, 0.9810) /0.047	-3.4548 (-6.5666, -0.3430) /0.030	0.2169 (0.0474, 0.9917) /0.049	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
Female	0/ 99	3/104 (3%)	<0.0001 (<0.0001, -) />0.999	-5.1377 (-25.6021, 15.3266) /0.623	<0.0001 (<0.0001, -) />0.999	0.142
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Decreased appetite						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Dehydration						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gout						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hyperglycaemia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertriglyceridaemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hypophosphataemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Increased appetite						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Diabetes mellitus						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Diabetic ketoacidosis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Hypokalaemia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impaired fasting glucose						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Type 2 diabetes mellitus						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin B12 deficiency						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Vitamin B6 deficiency						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
Female	12/ 99 (12%)	3/104 (3%)	4.6437 (1.2691, 16.9918) /0.020	9.2366 (2.0477, 16.4255) /0.012	4.2020 (1.2223, 14.4459) /0.023	0.115
Male	4/209 (2%)	4/204 (2%)	0.9756 (0.2407, 3.9544) /0.972	-0.0469 (-2.7059, 2.6121) /0.972	0.9761 (0.2474, 3.8505) /0.972	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign prostatic hyperplasia						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Menorrhagia						
Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	>0.999
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Balanoposthitis						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Cervical dysplasia						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysmenorrhoe ^a						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	>0.999
Male	0/209	0/204	NC	NC	NC	
Adenomyosis						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cyst						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Breast mass						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast pain Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Dysfunctional uterine bleeding Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital erythema						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Menometrorrhagia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menstrual disorder						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Metrorrhagia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst ruptured						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Penile pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scrotal mass						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Vaginal discharge						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal haemorrhage						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
Female	5/ 99 (5%)	9/104 (9%)	0.5615 (0.1814, 1.7377) /0.317	-3.6033 (-10.5175, 3.3109) /0.307	0.5836 (0.2026, 1.6812) /0.318	0.384
Male	4/209 (2%)	3/204 (1%)	1.3073 (0.2889, 5.9151) /0.728	0.4433 (-2.0425, 2.9290) /0.727	1.3014 (0.2949, 5.7427) /0.728	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia Female	3/ 99 (3%)	5/104 (5%)	0.6188 (0.1439, 2.6607) /0.519	-1.7774 (-7.0978, 3.5430) /0.513	0.6303 (0.1547, 2.5679) /0.520	0.191
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.317
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphadenopathy						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anaemia folate deficiency						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Deficiency anaemia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Eosinophilia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Leukocytosis Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Microcytic anaemia Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neutropenia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Thrombocytopenia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
Female	4/ 99 (4%)	4/104 (4%)	1.0526 (0.2560, 4.3291) /0.943	0.1943 (-5.1634, 5.5519) /0.943	1.0505 (0.2701, 4.0860) /0.943	0.278
Male	9/209 (4%)	3/204 (1%)	3.0150 (0.8044, 11.3002) /0.102	2.8356 (-0.3741, 6.0454) /0.083	2.9282 (0.8042, 10.6624) /0.103	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension						
Female	3/ 99 (3%)	1/104 (<1%)	3.2187 (0.3292, 31.4746) /0.315	2.0688 (-1.7938, 5.9313) /0.294	3.1515 (0.3334, 29.7926) /0.317	0.958
Male	6/209 (3%)	2/204 (<1%)	2.9852 (0.5954, 14.9661) /0.184	1.8904 (-0.7465, 4.5273) /0.160	2.9282 (0.5980, 14.3397) /0.185	
Deep vein thrombosis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypertensive crisis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orthostatic hypotension						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Phlebitis						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Varicophlebitis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Varicose vein						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Venous thrombosis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
Female	3/ 99 (3%)	1/104 (<1%)	3.2187 (0.3292, 31.4746) /0.315	2.0688 (-1.7938, 5.9313) /0.294	3.1515 (0.3334, 29.7926) /0.317	0.636
Male	9/209 (4%)	5/204 (2%)	1.7910 (0.5898, 5.4383) /0.304	1.8552 (-1.6199, 5.3303) /0.295	1.7569 (0.5990, 5.1533) /0.305	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.327
Male	3/209 (1%)	2/204 (<1%)	1.4709 (0.2432, 8.8955) /0.674	0.4550 (-1.6494, 2.5594) /0.672	1.4641 (0.2472, 8.6713) /0.674	
Pollakiuria						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.317
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal colic						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Haematuria						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Renal impairment						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic kidney disease						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Micturition urgency						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral discharge						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
Female	3/ 99 (3%)	2/104 (2%)	1.5937 (0.2606, 9.7460) /0.614	1.1072 (-3.1787, 5.3931) /0.613	1.5758 (0.2690, 9.2316) /0.614	0.273
Male	4/209 (2%)	8/204 (4%)	0.4780 (0.1417, 1.6129) /0.234	-2.0077 (-5.2551, 1.2397) /0.226	0.4880 (0.1493, 1.5956) /0.235	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Conjunctivitis allergic						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pruritus						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Eyelid oedema						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vision blurred						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Blepharitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cataract subcapsular Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctival haemorrhage						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Dry eye						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Eye swelling						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lacrimation increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Ocular hyperaemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous haematoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.887
Male	8/209 (4%)	6/204 (3%)	1.3134 (0.4476, 3.8543) /0.620	0.8866 (-2.5979, 4.3711) /0.618	1.3014 (0.4596, 3.6849) /0.620	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.174
Male	4/209 (2%)	2/204 (<1%)	1.9707 (0.3570, 10.8794) /0.436	0.9335 (-1.3640, 3.2310) /0.426	1.9522 (0.3615, 10.5414) /0.437	
Lipoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Basal cell carcinoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Fibrous histiocyoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Knuckle pads						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Melanocytic naevus						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Papillary thyroid cancer						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Seminoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin papilloma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Squamous cell carcinoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Squamous cell carcinoma of skin						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	7/209 (3%)	2/204 (<1%)	3.5000 (0.7184, 17.0523) /0.121	2.3689 (-0.4200, 5.1578) /0.096	3.4163 (0.7182, 16.2506) /0.123	
Tinnitus						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Deafness						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear discomfort						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Ear pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Excessive cerumen production						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vertigo positional						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.230
Male	4/209 (2%)	2/204 (<1%)	1.9707 (0.3570, 10.8794) /0.436	0.9335 (-1.3640, 3.2310) /0.426	1.9522 (0.3615, 10.5414) /0.437	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.179
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	
Allergy to animal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Drug hypersensitivity						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Mycotic allergy						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	4/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bradycardia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cardiovascular disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Palpitations						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Sinus tachycardia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ventricular extrasystoles						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.971
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidism						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypogonadism						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thyroid mass Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Biliary tract disorder						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Cholecystitis acute						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hepatocellular injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hyperbilirubinaemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	>0.999
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abortion missed						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Abortion spontaneous						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Social circumstances						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menopause Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Stress at work Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Dental implantation						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	209/214 (98%)	150/207 (72%)	15.8840 (6.2177, 40.5779) /<.001	25.1998 (18.7868, 31.6127) /<.001	1.3478 (1.2361, 1.4695) /<.001	0.709
Non-White	85/ 94 (90%)	70/101 (69%)	4.1825 (1.8667, 9.3713) /<.001	21.1186 (10.3348, 31.9024) /<.001	1.3047 (1.1280, 1.5091) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	136/214 (64%)	112/207 (54%)	1.4789 (1.0012, 2.1847) /0.049	9.4451 (0.0823, 18.8079) /0.048	1.1746 (0.9995, 1.3802) /0.051	0.654
Non-White	53/ 94 (56%)	52/101 (51%)	1.2181 (0.6928, 2.1417) /0.493	4.8978 (-9.0844, 18.8801) /0.492	1.0951 (0.8446, 1.4199) /0.493	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
White	39/214 (18%)	30/207 (14%)	1.3149 (0.7819, 2.2112) /0.302	3.7315 (-3.3218, 10.7849) /0.300	1.2575 (0.8132, 1.9446) /0.303	0.859
Non-White	13/ 94 (14%)	12/101 (12%)	1.1903 (0.5137, 2.7582) /0.684	1.9486 (-7.4600, 11.3572) /0.685	1.1640 (0.5595, 2.4217) /0.685	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
White	19/214 (9%)	12/207 (6%)	1.5833 (0.7483, 3.3501) /0.229	3.0814 (-1.8842, 8.0470) /0.224	1.5315 (0.7628, 3.0749) /0.231	0.486
Non-White	13/ 94 (14%)	13/101 (13%)	1.0864 (0.4757, 2.4813) /0.844	0.9585 (-8.5995, 10.5165) /0.844	1.0745 (0.5253, 2.1977) /0.844	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza						
White	12/214 (6%)	11/207 (5%)	1.0585 (0.4563, 2.4553) /0.895	0.2935 (-4.0469, 4.6339) /0.895	1.0552 (0.4763, 2.3379) /0.895	0.516
Non-White	5/ 94 (5%)	3/101 (3%)	1.8352 (0.4263, 7.9011) /0.415	2.3489 (-3.2675, 7.9652) /0.412	1.7908 (0.4400, 7.2876) /0.416	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
White	10/214 (5%)	14/207 (7%)	0.6758 (0.2932, 1.5576) /0.358	-2.0904 (-6.5287, 2.3479) /0.356	0.6909 (0.3140, 1.5204) /0.358	0.574
Non-White	1/ 94 (1%)	3/101 (3%)	0.3513 (0.0359, 3.4372) /0.369	-1.9065 (-5.8133, 2.0003) /0.339	0.3582 (0.0379, 3.3834) /0.370	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis						
White	11/214 (5%)	9/207 (4%)	1.1921 (0.4835, 2.9393) /0.703	0.7924 (-3.2660, 4.8507) /0.702	1.1822 (0.5003, 2.7937) /0.703	0.614
Non-White	2/ 94 (2%)	3/101 (3%)	0.7101 (0.1160, 4.3466) /0.711	-0.8426 (-5.2553, 3.5700) /0.708	0.7163 (0.1224, 4.1928) /0.711	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
White	8/214 (4%)	10/207 (5%)	0.7651 (0.2959, 1.9782) /0.581	-1.0926 (-4.9645, 2.7793) /0.580	0.7738 (0.3115, 1.9222) /0.581	0.764
Non-White	2/ 94 (2%)	2/101 (2%)	1.0761 (0.1485, 7.7970) /0.942	0.1475 (-3.8391, 4.1340) /0.942	1.0745 (0.1544, 7.4749) /0.942	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis						
White	6/214 (3%)	8/207 (4%)	0.7175 (0.2446, 2.1049) /0.546	-1.0610 (-4.4942, 2.3722) /0.545	0.7255 (0.2561, 2.0548) /0.546	0.763
Non-White	2/ 94 (2%)	4/101 (4%)	0.5272 (0.0943, 2.9475) /0.466	-1.8327 (-6.6261, 2.9606) /0.454	0.5372 (0.1007, 2.8652) /0.467	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.043
Non-White	11/ 94 (12%)	6/101 (6%)	2.0984 (0.7436, 5.9214) /0.161	5.7615 (-2.2058, 13.7289) /0.156	1.9699 (0.7586, 5.1151) /0.164	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis						
White	4/214 (2%)	7/207 (3%)	0.5442 (0.1569, 1.8875) /0.338	-1.5125 (-4.5712, 1.5463) /0.332	0.5527 (0.1642, 1.8601) /0.338	0.734
Non-White	1/ 94 (1%)	3/101 (3%)	0.3513 (0.0359, 3.4372) /0.369	-1.9065 (-5.8133, 2.0003) /0.339	0.3582 (0.0379, 3.3834) /0.370	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis						
White	7/214 (3%)	5/207 (2%)	1.3662 (0.4266, 4.3750) /0.599	0.8556 (-2.3152, 4.0264) /0.597	1.3542 (0.4367, 4.1990) /0.599	0.292
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Syphilis						
White	3/214 (1%)	8/207 (4%)	0.3537 (0.0925, 1.3520) /0.129	-2.4629 (-5.5249, 0.5992) /0.115	0.3627 (0.0976, 1.3485) /0.130	0.491
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
White	8/214 (4%)	4/207 (2%)	1.9709 (0.5843, 6.6476) /0.274	1.8060 (-1.3526, 4.9645) /0.262	1.9346 (0.5915, 6.3269) /0.275	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Lower respiratory tract infection						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.177
Non-White	6/ 94 (6%)	4/101 (4%)	1.6534 (0.4517, 6.0525) /0.448	2.4226 (-3.8133, 8.6585) /0.446	1.6117 (0.4694, 5.5337) /0.448	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
White	7/214 (3%)	2/207 (<1%)	3.4662 (0.7116, 16.8836) /0.124	2.3048 (-0.4256, 5.0353) /0.098	3.3855 (0.7116, 16.1080) /0.125	0.110
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
White	6/214 (3%)	3/207 (1%)	1.9615 (0.4840, 7.9488) /0.345	1.3545 (-1.3919, 4.1008) /0.334	1.9346 (0.4903, 7.6336) /0.346	0.169
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Oral herpes						
White	3/214 (1%)	5/207 (2%)	0.5744 (0.1355, 2.4349) /0.452	-1.0136 (-3.6319, 1.6047) /0.448	0.5804 (0.1405, 2.3976) /0.452	0.060
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes zoster						
White	5/214 (2%)	2/207 (<1%)	2.4522 (0.4704, 12.7824) /0.287	1.3703 (-1.0529, 3.7934) /0.268	2.4182 (0.4744, 12.3257) /0.288	0.620
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Rhinitis						
White	3/214 (1%)	4/207 (2%)	0.7216 (0.1595, 3.2640) /0.672	-0.5305 (-2.9796, 1.9186) /0.671	0.7255 (0.1644, 3.2020) /0.672	0.806
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
White	4/214 (2%)	1/207 (<1%)	3.9238 (0.4349, 35.4025) /0.223	1.3861 (-0.6596, 3.4317) /0.184	3.8692 (0.4361, 34.3292) /0.224	0.376
Non-White	2/ 94 (2%)	2/101 (2%)	1.0761 (0.1485, 7.7970) /0.942	0.1475 (-3.8391, 4.1340) /0.942	1.0745 (0.1544, 7.4749) /0.942	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydial infection						
White	5/214 (2%)	2/207 (<1%)	2.4522 (0.4704, 12.7824) /0.287	1.3703 (-1.0529, 3.7934) /0.268	2.4182 (0.4744, 12.3257) /0.288	0.148
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Gastroenteritis viral						
White	5/214 (2%)	1/207 (<1%)	4.9282 (0.5708, 42.5474) /0.147	1.8534 (-0.3801, 4.0868) /0.104	4.8364 (0.5699, 41.0460) /0.149	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	0.951
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute sinusitis						
White	3/214 (1%)	1/207 (<1%)	2.9289 (0.3022, 28.3869) /0.354	0.9188 (-0.9179, 2.7554) /0.327	2.9019 (0.3043, 27.6727) /0.354	0.146
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Furuncle						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.293
Non-White	2/ 94 (2%)	1/101 (<1%)	2.1739 (0.1939, 24.3767) /0.529	1.1376 (-2.3608, 4.6359) /0.524	2.1489 (0.1981, 23.3113) /0.529	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	0.293
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.146
Non-White	0/ 94	3/101 (3%)	<0.0001 (<0.0001, -) />0.999	-5.2206 (-26.2068, 15.7655) /0.626	<0.0001 (<0.0001, -) />0.999	
Cystitis						
White	3/214 (1%)	1/207 (<1%)	2.9289 (0.3022, 28.3869) /0.354	0.9188 (-0.9179, 2.7554) /0.327	2.9019 (0.3043, 27.6727) /0.354	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.202
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.021
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	
Onychomycosis						
White	1/214 (<1%)	3/207 (1%)	0.3192 (0.0329, 3.0942) /0.324	-0.9820 (-2.8489, 0.8850) /0.303	0.3224 (0.0338, 3.0747) /0.325	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Secondary syphilis						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Tinea versicolour						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.391
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth infection						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.391
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Acarodermatitis						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Candida infection						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Cellulitis						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Injection site abscess						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal gonococcal infection						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Otitis media						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis gonococcal						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Tinea cruris						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis						
White	0/214	3/207 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Urethritis gonococcal						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	
Anal abscess						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Chronic tonsillitis						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear infection						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Fungal infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes simplex						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Impetigo						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site cellulitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Orchitis						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis media acute						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Paronychia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pulpitis dental						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Staphylococcal infection						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.089
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	
Tooth abscess						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Urethritis chlamydial White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Abscess						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Acute hepatitis C						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amoebiasis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Anorectal human papilloma virus infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Appendicitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Cervicitis human papilloma virus						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Clostridium difficile colitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Conjunctivitis bacterial						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis infectious						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Epididymitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Folliculitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastric infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastrointestinal infection						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal viral infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Gingival abscess						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Groin abscess						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Herpes virus infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infected bite						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Infection						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infection parasitic						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Laryngitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Liver abscess						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Localised infection						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal herpes						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Oral candidiasis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Periodontitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Pertussis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pneumonia mycoplasmal						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Post procedural infection						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Primary syphilis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Proctitis chlamydial						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis herpes						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Pyelonephritis acute						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rotavirus infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Sexually transmitted disease						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin candida						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Staphylococcal skin infection						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Tinea pedis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tongue fungal infection						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Ureaplasma infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral tonsillitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Vulvovaginal candidiasis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginitis trichomonal						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
White	183/214 (86%)	12/207 (6%)	95.9274 (47.8163, 192.4465) /<.001	79.7169 (74.0274, 85.4065) /<.001	14.7512 (8.4944, 25.6164) /<.001	0.106
Non-White	69/ 94 (73%)	10/101 (10%)	25.1160 (11.3158, 55.7460) /<.001	63.5033 (52.8397, 74.1668) /<.001	7.4138 (4.0657, 13.5192) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
White	171/214 (80%)	0/207	>999 (>999, >999) /NC	NC	NC	NC
Non-White	60/ 94 (64%)	0/101	>999 (>999, >999) /NC	NC	NC	
Injection site nodule						
White	24/214 (11%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	13/ 94 (14%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
White	23/214 (11%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	7/ 94 (7%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pyrexia						
White	17/214 (8%)	7/207 (3%)	2.4656 (1.0005, 6.0759) /0.050	4.5623 (0.1816, 8.9430) /0.041	2.3491 (0.9948, 5.5470) /0.051	0.926
Non-White	4/ 94 (4%)	2/101 (2%)	2.2000 (0.3935, 12.3009) /0.369	2.2751 (-2.6272, 7.1774) /0.363	2.1489 (0.4029, 11.4610) /0.370	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
White	19/214 (9%)	3/207 (1%)	6.6256 (1.9301, 22.7442) /0.003	7.4292 (3.2852, 11.5733) /<.001	6.1262 (1.8404, 20.3918) /0.003	0.084
Non-White	3/ 94 (3%)	3/101 (3%)	1.0769 (0.2119, 5.4720) /0.929	0.2212 (-4.6356, 5.0779) /0.929	1.0745 (0.2223, 5.1929) /0.929	
Injection site swelling						
White	18/214 (8%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	5/ 94 (5%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
White	7/214 (3%)	2/207 (<1%)	3.4662 (0.7116, 16.8836) /0.124	2.3048 (-0.4256, 5.0353) /0.098	3.3855 (0.7116, 16.1080) /0.125	0.860
Non-White	4/ 94 (4%)	1/101 (<1%)	4.4444 (0.4877, 40.5035) /0.186	3.2652 (-1.2490, 7.7795) /0.156	4.2979 (0.4891, 37.7637) /0.188	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
White	12/214 (6%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
White	6/214 (3%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	4/ 94 (4%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pain						
White	5/214 (2%)	1/207 (<1%)	4.9282 (0.5708, 42.5474) /0.147	1.8534 (-0.3801, 4.0868) /0.104	4.8364 (0.5699, 41.0460) /0.149	0.330
Non-White	3/ 94 (3%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Chills						
White	6/214 (3%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site haematoma						
White	6/214 (3%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pruritus						
White	6/214 (3%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Asthenia						
White	6/214 (3%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site warmth						
White	5/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site reaction						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.202
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	
Chest pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cyst						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Discomfort						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Oedema peripheral						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Feeling of body temperature change						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site anaesthesia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Injection site discolouration						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discomfort						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Non-cardiac chest pain						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peripheral swelling						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Vessel puncture site pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	47/214 (22%)	30/207 (14%)	1.6605 (1.0026, 2.7499) /0.049	7.4699 (0.1375, 14.8022) /0.046	1.5154 (0.9994, 2.2978) /0.050	0.609
Non-White	27/ 94 (29%)	16/101 (16%)	2.1409 (1.0670, 4.2954) /0.032	12.8818 (1.2898, 24.4738) /0.029	1.8132 (1.0452, 3.1454) /0.034	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
White	16/214 (7%)	10/207 (5%)	1.5919 (0.7051, 3.5940) /0.263	2.6457 (-1.9314, 7.2228) /0.257	1.5477 (0.7190, 3.3314) /0.264	0.796
Non-White	6/ 94 (6%)	5/101 (5%)	1.3091 (0.3859, 4.4410) /0.666	1.4325 (-5.0726, 7.9376) /0.666	1.2894 (0.4070, 4.0847) /0.666	
Nausea						
White	10/214 (5%)	4/207 (2%)	2.4877 (0.7677, 8.0613) /0.129	2.7405 (-0.6525, 6.1336) /0.113	2.4182 (0.7706, 7.5891) /0.130	0.636
Non-White	4/ 94 (4%)	1/101 (<1%)	4.4444 (0.4877, 40.5035) /0.186	3.2652 (-1.2490, 7.7795) /0.156	4.2979 (0.4891, 37.7637) /0.188	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache						
White	4/214 (2%)	4/207 (2%)	0.9667 (0.2386, 3.9172) /0.962	-0.0632 (-2.6727, 2.5463) /0.962	0.9673 (0.2451, 3.8168) /0.962	0.670
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
White	3/214 (1%)	3/207 (1%)	0.9668 (0.1929, 4.8457) /0.967	-0.0474 (-2.3127, 2.2179) /0.967	0.9673 (0.1975, 4.7379) /0.967	0.374
Non-White	3/ 94 (3%)	1/101 (<1%)	3.2967 (0.3369, 32.2603) /0.305	2.2014 (-1.8427, 6.2455) /0.286	3.2234 (0.3412, 30.4507) /0.307	
Dyspepsia						
White	5/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.026
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	2/ 94 (2%)	3/101 (3%)	0.7101 (0.1160, 4.3466) /0.711	-0.8426 (-5.2553, 3.5700) /0.708	0.7163 (0.1224, 4.1928) /0.711	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
White	4/214 (2%)	2/207 (<1%)	1.9524 (0.3537, 10.7758) /0.443	0.9030 (-1.3483, 3.1543) /0.432	1.9346 (0.3582, 10.4487) /0.443	0.370
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.192
Non-White	3/ 94 (3%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Haemorrhoids						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	0.134
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis						
White	1/214 (<1%)	3/207 (1%)	0.3192 (0.0329, 3.0942) /0.324	-0.9820 (-2.8489, 0.8850) /0.303	0.3224 (0.0338, 3.0747) /0.325	0.495
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Flatulence						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.322
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Gastritis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Inguinal hernia						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Abdominal discomfort						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.089
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Abdominal pain upper						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aphthous ulcer						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Colitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Dental caries						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Enteritis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Odynophagia						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal distension						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Abdominal hernia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal pruritus						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Anal skin tags						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal discomfort						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Chronic gastritis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphagia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Eosinophilic oesophagitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epigastric discomfort						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Functional gastrointestinal disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Haemorrhoids thrombosed						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Irritable bowel syndrome						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Lip dry						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip swelling						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Mouth ulceration						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Oral pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pancreatitis acute						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis chronic						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Proctitis ulcerative						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Steatorrhoea						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tongue ulceration						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Tooth impacted						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Umbilical hernia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	49/214 (23%)	28/207 (14%)	1.8985 (1.1398, 3.1623) /0.014	9.3706 (2.0633, 16.6780) /0.012	1.6928 (1.1087, 2.5845) /0.015	0.659
Non-White	20/ 94 (21%)	15/101 (15%)	1.5495 (0.7407, 3.2415) /0.245	6.4251 (-4.3706, 17.2208) /0.243	1.4326 (0.7802, 2.6305) /0.246	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
White	13/214 (6%)	8/207 (4%)	1.6088 (0.6526, 3.9661) /0.302	2.2100 (-1.9297, 6.3497) /0.295	1.5718 (0.6653, 3.7136) /0.303	0.236
Non-White	8/ 94 (9%)	2/101 (2%)	4.6047 (0.9521, 22.2704) /0.058	6.5304 (0.2693, 12.7916) /0.041	4.2979 (0.9364, 19.7259) /0.061	
Arthralgia						
White	4/214 (2%)	6/207 (3%)	0.6381 (0.1774, 2.2947) /0.491	-1.0294 (-3.9476, 1.8888) /0.489	0.6449 (0.1846, 2.2522) /0.492	0.665
Non-White	2/ 94 (2%)	2/101 (2%)	1.0761 (0.1485, 7.7970) /0.942	0.1475 (-3.8391, 4.1340) /0.942	1.0745 (0.1544, 7.4749) /0.942	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
White	4/214 (2%)	5/207 (2%)	0.7695 (0.2037, 2.9064) /0.699	-0.5463 (-3.3152, 2.2226) /0.699	0.7738 (0.2107, 2.8418) /0.699	0.390
Non-White	1/ 94 (1%)	4/101 (4%)	0.2608 (0.0286, 2.3762) /0.233	-2.8966 (-7.2287, 1.4356) /0.190	0.2686 (0.0306, 2.3602) /0.236	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
White	4/214 (2%)	4/207 (2%)	0.9667 (0.2386, 3.9172) /0.962	-0.0632 (-2.6727, 2.5463) /0.962	0.9673 (0.2451, 3.8168) /0.962	0.591
Non-White	2/ 94 (2%)	4/101 (4%)	0.5272 (0.0943, 2.9475) /0.466	-1.8327 (-6.6261, 2.9606) /0.454	0.5372 (0.1007, 2.8652) /0.467	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
White	7/214 (3%)	1/207 (<1%)	6.9662 (0.8495, 57.1236) /0.071	2.7879 (0.2244, 5.3515) /0.033	6.7710 (0.8404, 54.5551) /0.072	0.287
Non-White	3/ 94 (3%)	2/101 (2%)	1.6319 (0.2666, 9.9883) /0.596	1.2113 (-3.2618, 5.6844) /0.596	1.6117 (0.2753, 9.4338) /0.597	
Muscle spasms						
White	1/214 (<1%)	4/207 (2%)	0.2383 (0.0264, 2.1497) /0.201	-1.4651 (-3.5511, 0.6210) /0.169	0.2418 (0.0273, 2.1456) /0.202	0.095
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.202
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.175
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Osteoarthritis						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	2/ 94 (2%)	2/101 (2%)	1.0761 (0.1485, 7.7970) /0.942	0.1475 (-3.8391, 4.1340) /0.942	1.0745 (0.1544, 7.4749) /0.942	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tendonitis						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Joint swelling						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.322
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal pain						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Arthropathy						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bursitis						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Foot deformity						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intervertebral disc protrusion						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Osteopenia						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Arthritis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Costochondritis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dupuytren's contracture						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Exostosis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flank pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Intervertebral disc disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint effusion						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Muscle tightness						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Myositis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteonecrosi s						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Patellofemor al pain syndrome						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Polyarthriti s						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Rhabdomyolys is						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Scoliosis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Spinal osteoarthritis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Synovial cyst						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Temporomandibular joint syndrome						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tenosynovitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
White	47/214 (22%)	26/207 (13%)	1.9592 (1.1611, 3.3060) /0.012	9.4022 (2.2505, 16.5540) /0.010	1.7486 (1.1269, 2.7131) /0.013	0.738
Non-White	17/ 94 (18%)	9/101 (9%)	2.2568 (0.9523, 5.3483) /0.064	9.1742 (-0.3868, 18.7352) /0.060	2.0296 (0.9515, 4.3292) /0.067	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
White	24/214 (11%)	15/207 (7%)	1.6168 (0.8228, 3.1773) /0.163	3.9686 (-1.5402, 9.4774) /0.158	1.5477 (0.8358, 2.8660) /0.165	0.098
Non-White	10/ 94 (11%)	2/101 (2%)	5.8929 (1.2560, 27.6469) /0.025	8.6581 (1.8587, 15.4575) /0.013	5.3723 (1.2084, 23.8846) /0.027	
Dizziness						
White	6/214 (3%)	2/207 (<1%)	2.9567 (0.5899, 14.8199) /0.187	1.8376 (-0.7446, 4.4197) /0.163	2.9019 (0.5924, 14.2138) /0.189	0.377
Non-White	3/ 94 (3%)	3/101 (3%)	1.0769 (0.2119, 5.4720) /0.929	0.2212 (-4.6356, 5.0779) /0.929	1.0745 (0.2223, 5.1929) /0.929	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica						
White	6/214 (3%)	1/207 (<1%)	5.9423 (0.7092, 49.7917) /0.100	2.3206 (-0.0843, 4.7256) /0.059	5.8037 (0.7048, 47.7922) /0.102	0.575
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Paraesthesia						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.951
Non-White	2/ 94 (2%)	1/101 (<1%)	2.1739 (0.1939, 24.3767) /0.529	1.1376 (-2.3608, 4.6359) /0.524	2.1489 (0.1981, 23.3113) /0.529	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine						
White	4/214 (2%)	1/207 (<1%)	3.9238 (0.4349, 35.4025) /0.223	1.3861 (-0.6596, 3.4317) /0.184	3.8692 (0.4361, 34.3292) /0.224	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Cervicobrachial syndrome						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Neuralgia						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Syncope						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia ^a						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Presyncope						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Somnolence						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Anterograde amnesia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Autonomic nervous system imbalance						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Burning sensation						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cerebral cyst						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Cerebrovascular accident						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cognitive disorder						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Disturbance in attention						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysaesthesia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Dysgeusia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dystonia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Essential tremor						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Facial paralysis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Intercostal neuralgia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Loss of consciousness						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Memory impairment						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Muscle contractions involuntary						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Neuromuscular blockade						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post herpetic neuralgia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Post-traumatic headache						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seizure						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Tension headache						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
White	22/214 (10%)	24/207 (12%)	0.8737 (0.4733, 1.6127) /0.666	-1.3138 (-7.2786, 4.6509) /0.666	0.8867 (0.5136, 1.5308) /0.666	0.451
Non-White	14/ 94 (15%)	12/101 (12%)	1.2979 (0.5671, 2.9708) /0.537	3.0124 (-6.5594, 12.5843) /0.537	1.2535 (0.6114, 2.5703) /0.537	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
White	7/214 (3%)	8/207 (4%)	0.8412 (0.2994, 2.3630) /0.743	-0.5937 (-4.1398, 2.9524) /0.743	0.8464 (0.3125, 2.2920) /0.743	0.367
Non-White	9/ 94 (10%)	6/101 (6%)	1.6765 (0.5730, 4.9054) /0.346	3.6339 (-3.8917, 11.1594) /0.344	1.6117 (0.5964, 4.3551) /0.347	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
White	6/214 (3%)	8/207 (4%)	0.7175 (0.2446, 2.1049) /0.546	-1.0610 (-4.4942, 2.3722) /0.545	0.7255 (0.2561, 2.0548) /0.546	0.684
Non-White	3/ 94 (3%)	3/101 (3%)	1.0769 (0.2119, 5.4720) /0.929	0.2212 (-4.6356, 5.0779) /0.929	1.0745 (0.2223, 5.1929) /0.929	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
White	1/214 (<1%)	3/207 (1%)	0.3192 (0.0329, 3.0942) /0.324	-0.9820 (-2.8489, 0.8850) /0.303	0.3224 (0.0338, 3.0747) /0.325	0.505
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	0.134
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Respiratory disorder						
White	2/214 (<1%)	3/207 (1%)	0.6415 (0.1061, 3.8789) /0.629	-0.5147 (-2.5914, 1.5620) /0.627	0.6449 (0.1089, 3.8200) /0.629	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	0.175
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Catarrh						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphonia						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.290
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract congestion						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.322
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Dyspnoea						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Productive cough						
White	0/214	0/207	NC	NC	NC	NC
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Respiratory tract congestion						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhinitis allergic						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Bronchospasm						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Emphysema						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Lung disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal obstruction						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nasal septum deviation						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Pulmonary mass						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reflux laryngitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Respiratory distress						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Sleep apnoea syndrome						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wheezing White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
White	31/214 (14%)	23/207 (11%)	1.3552 (0.7611, 2.4129) /0.302	3.3749 (-2.9942, 9.7440) /0.299	1.3037 (0.7873, 2.1590) /0.303	0.405
Non-White	6/ 94 (6%)	8/101 (8%)	0.7926 (0.2644, 2.3761) /0.678	-1.5378 (-8.7600, 5.6844) /0.676	0.8059 (0.2904, 2.2360) /0.678	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
White	3/214 (1%)	2/207 (<1%)	1.4573 (0.2410, 8.8119) /0.682	0.4357 (-1.6275, 2.4989) /0.679	1.4509 (0.2449, 8.5949) /0.682	0.118
Non-White	3/ 94 (3%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
White	1/214 (<1%)	4/207 (2%)	0.2383 (0.0264, 2.1497) /0.201	-1.4651 (-3.5511, 0.6210) /0.169	0.2418 (0.0273, 2.1456) /0.202	0.160
Non-White	2/ 94 (2%)	1/101 (<1%)	2.1739 (0.1939, 24.3767) /0.529	1.1376 (-2.3608, 4.6359) /0.524	2.1489 (0.1981, 23.3113) /0.529	
Contusion						
White	3/214 (1%)	3/207 (1%)	0.9668 (0.1929, 4.8457) /0.967	-0.0474 (-2.3127, 2.2179) /0.967	0.9673 (0.1975, 4.7379) /0.967	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	0.259
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Procedural pain						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	0.427
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Epicondylitis						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exposure to communicable disease						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Limb injury						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Road traffic accident						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Animal bite						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bone contusion						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Hand fracture						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection related reaction						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Radius fracture						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Soft tissue injury						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Thermal burn						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Upper limb fracture						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Buttock injury						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye injury						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Facial bones fracture						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Humerus fracture						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury corneal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Joint dislocation						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament rupture						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Meniscus injury						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Post procedural complication						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Skin abrasion						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin injury						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Skull fracture						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Splinter White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Tendon rupture White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth fracture						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	28/214 (13%)	18/207 (9%)	1.5806 (0.8454, 2.9553) /0.152	4.3885 (-1.5401, 10.3170) /0.147	1.5047 (0.8591, 2.6354) /0.153	0.830
Non-White	8/ 94 (9%)	5/101 (5%)	1.7860 (0.5629, 5.6668) /0.325	3.5601 (-3.4909, 10.6112) /0.322	1.7191 (0.5830, 5.0698) /0.326	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
White	6/214 (3%)	3/207 (1%)	1.9615 (0.4840, 7.9488) /0.345	1.3545 (-1.3919, 4.1008) /0.334	1.9346 (0.4903, 7.6336) /0.346	0.169
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
White	4/214 (2%)	3/207 (1%)	1.2952 (0.2863, 5.8590) /0.737	0.4199 (-2.0180, 2.8577) /0.736	1.2897 (0.2922, 5.6924) /0.737	0.292
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lipase increased						
White	5/214 (2%)	2/207 (<1%)	2.4522 (0.4704, 12.7824) /0.287	1.3703 (-1.0529, 3.7934) /0.268	2.4182 (0.4744, 12.3257) /0.288	0.410
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Alanine aminotransferase increased						
White	4/214 (2%)	1/207 (<1%)	3.9238 (0.4349, 35.4025) /0.223	1.3861 (-0.6596, 3.4317) /0.184	3.8692 (0.4361, 34.3292) /0.224	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood pressure increased						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	0.078
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
White	3/214 (1%)	1/207 (<1%)	2.9289 (0.3022, 28.3869) /0.354	0.9188 (-0.9179, 2.7554) /0.327	2.9019 (0.3043, 27.6727) /0.354	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Blood cholesterol increased						
White	0/214	4/207 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
White	4/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine decreased						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Electrocardiogram QT prolonged						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Low density lipoprotein increased						
White	0/214	3/207 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood phosphorus decreased						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Blood triglycerides increased						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D decreased						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) />0.959	0.0737 (-2.7599, 2.9074) />0.959	1.0745 (0.0682, 16.9347) />0.959	
Weight decreased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Activated partial thromboplastin time prolonged						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Blood bilirubin increased						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatinine increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Blood triglycerides						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

ECG signs of ventricular hypertrophy						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Glycosylated haemoglobin increased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic enzyme increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Lipids increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Liver function test abnormal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Neisseria test positive						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatic enzymes increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Thyroxine free decreased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Weight increased						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
White	26/214 (12%)	14/207 (7%)	1.9065 (0.9658, 3.7635) /0.063	5.3862 (-0.1691, 10.9416) /0.057	1.7964 (0.9654, 3.3427) /0.064	0.599
Non-White	10/ 94 (11%)	8/101 (8%)	1.3839 (0.5218, 3.6704) /0.514	2.7175 (-5.4428, 10.8778) /0.514	1.3431 (0.5536, 3.2583) /0.514	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
White	7/214 (3%)	1/207 (<1%)	6.9662 (0.8495, 57.1236) /0.071	2.7879 (0.2244, 5.3515) /0.033	6.7710 (0.8404, 54.5551) /0.072	0.204
Non-White	4/ 94 (4%)	3/101 (3%)	1.4519 (0.3163, 6.6651) /0.632	1.2850 (-3.9697, 6.5397) /0.632	1.4326 (0.3293, 6.2330) /0.632	
Pruritus						
White	4/214 (2%)	3/207 (1%)	1.2952 (0.2863, 5.8590) /0.737	0.4199 (-2.0180, 2.8577) /0.736	1.2897 (0.2922, 5.6924) /0.737	0.152
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema						
White	4/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Acne						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.202
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash pruritic						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.958
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Alopecia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.322
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.290
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rash generalised						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.322
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seborrhoeic dermatitis						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Ecchymosis						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urticaria						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Decubitus ulcer						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Dermatitis acneiform White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis contact						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Intertrigo						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nail bed bleeding						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Neurodermatitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychoclasia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Photosensitivity reaction						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Purpura						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash erythematous						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Rash maculo-papular						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sebacous hyperplasia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Seborrhoea						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin fissures						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Skin lesion						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin mass						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Stasis dermatitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
White	24/214 (11%)	16/207 (8%)	1.5079 (0.7765, 2.9282) /0.225	3.4855 (-2.0921, 9.0631) /0.221	1.4509 (0.7939, 2.6518) /0.226	0.598
Non-White	8/ 94 (9%)	8/101 (8%)	1.0814 (0.3888, 3.0077) /0.881	0.5898 (-7.1277, 8.3074) /0.881	1.0745 (0.4202, 2.7475) /0.881	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia						
White	11/214 (5%)	2/207 (<1%)	5.5542 (1.2159, 25.3717) /0.027	4.1740 (0.9292, 7.4188) /0.012	5.3201 (1.1937, 23.7115) /0.028	0.430
Non-White	4/ 94 (4%)	2/101 (2%)	2.2000 (0.3935, 12.3009) /0.369	2.2751 (-2.6272, 7.1774) /0.363	2.1489 (0.4029, 11.4610) /0.370	
Anxiety						
White	7/214 (3%)	6/207 (3%)	1.1329 (0.3743, 3.4291) /0.825	0.3725 (-2.9295, 3.6744) /0.825	1.1285 (0.3857, 3.3017) /0.825	0.974
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
White	1/214 (<1%)	3/207 (1%)	0.3192 (0.0329, 3.0942) /0.324	-0.9820 (-2.8489, 0.8850) /0.303	0.3224 (0.0338, 3.0747) /0.325	0.579
Non-White	2/ 94 (2%)	3/101 (3%)	0.7101 (0.1160, 4.3466) /0.711	-0.8426 (-5.2553, 3.5700) /0.708	0.7163 (0.1224, 4.1928) /0.711	
Abnormal dreams						
White	3/214 (1%)	2/207 (<1%)	1.4573 (0.2410, 8.8119) /0.682	0.4357 (-1.6275, 2.4989) /0.679	1.4509 (0.2449, 8.5949) /0.682	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	0.259
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depressed mood						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.202
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Drug abuse						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	2/ 94 (2%)	1/101 (<1%)	2.1739 (0.1939, 24.3767) /0.529	1.1376 (-2.3608, 4.6359) /0.524	2.1489 (0.1981, 23.3113) /0.529	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Suicidal ideation						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.290
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Acute stress disorder						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Adjustment disorder						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Affect lability						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Anxiety disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depression suicidal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Drug dependence						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritability						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Mood altered						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mood swings						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Panic disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Suicidal behaviour						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Suicide attempt						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Thinking abnormal White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
White	8/214 (4%)	9/207 (4%)	0.8544 (0.3232, 2.2586) /0.751	-0.6095 (-4.3748, 3.1558) /0.751	0.8598 (0.3382, 2.1858) /0.751	0.176
Non-White	6/ 94 (6%)	18/101 (18%)	0.3144 (0.1190, 0.8305) /0.020	-11.4388 (-20.3900, -2.4876) /0.012	0.3582 (0.1485, 0.8637) /0.022	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
White	3/214 (1%)	4/207 (2%)	0.7216 (0.1595, 3.2640) /0.672	-0.5305 (-2.9796, 1.9186) /0.671	0.7255 (0.1644, 3.2020) /0.672	0.934
Non-White	5/ 94 (5%)	8/101 (8%)	0.6531 (0.2059, 2.0720) /0.470	-2.6016 (-9.5530, 4.3497) /0.463	0.6715 (0.2277, 1.9804) /0.471	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	4/101 (4%)	0.2608 (0.0286, 2.3762) /0.233	-2.8966 (-7.2287, 1.4356) /0.190	0.2686 (0.0306, 2.3602) /0.236	
Decreased appetite						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.089
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dehydration						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Gout						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperglycaemia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Hypertriglyceridaemia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphat aemia						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Increased appetite						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetes mellitus						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Diabetic ketoacidosis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypokalaemia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Impaired fasting glucose						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Vitamin B12 deficiency						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B6 deficiency						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
White	11/214 (5%)	4/207 (2%)	2.7500 (0.8614, 8.7793) /0.088	3.2078 (-0.2950, 6.7106) /0.073	2.6600 (0.8607, 8.2207) /0.089	0.668
Non-White	5/ 94 (5%)	3/101 (3%)	1.8352 (0.4263, 7.9011) /0.415	2.3489 (-3.2675, 7.9652) /0.412	1.7908 (0.4400, 7.2876) /0.416	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Benign prostatic hyperplasia						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Menorrhagia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.322
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Balanoposthitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Cervical dysplasia						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysmenorrhoe						
^a White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Adenomyosis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cyst						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Breast mass						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast pain						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Dysfunctional uterine bleeding						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital erythema						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Menometrorrhagia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menstrual disorder						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Metrorrhagia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ovarian cyst ruptured						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Penile pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scrotal mass						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Vaginal discharge						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal haemorrhage						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
White	6/214 (3%)	5/207 (2%)	1.1654 (0.3501, 3.8789) /0.803	0.3883 (-2.6557, 3.4323) /0.803	1.1607 (0.3598, 3.7449) /0.803	0.296
Non-White	3/ 94 (3%)	7/101 (7%)	0.4427 (0.1111, 1.7648) /0.248	-3.7392 (-9.8351, 2.3567) /0.229	0.4605 (0.1226, 1.7290) /0.251	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.051
Non-White	2/ 94 (2%)	5/101 (5%)	0.4174 (0.0790, 2.2052) /0.304	-2.8228 (-7.9616, 2.3159) /0.282	0.4298 (0.0854, 2.1622) /0.306	
Iron deficiency anaemia						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphadenopathy						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anaemia folate deficiency						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Deficiency anaemia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Eosinophilia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Leukocytosis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Microcytic anaemia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neutropenia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Thrombocytopenia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
White	5/214 (2%)	5/207 (2%)	0.9665 (0.2756, 3.3889) /0.958	-0.0790 (-2.9894, 2.8314) /0.958	0.9673 (0.2842, 3.2921) /0.958	0.119
Non-White	8/ 94 (9%)	2/101 (2%)	4.6047 (0.9521, 22.2704) /0.058	6.5304 (0.2693, 12.7916) /0.041	4.2979 (0.9364, 19.7259) /0.061	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension						
White	4/214 (2%)	2/207 (<1%)	1.9524 (0.3537, 10.7758) /0.443	0.9030 (-1.3483, 3.1543) /0.432	1.9346 (0.3582, 10.4487) /0.443	0.449
Non-White	5/ 94 (5%)	1/101 (<1%)	5.6180 (0.6441, 49.0048) /0.118	4.3290 (-0.6014, 9.2595) /0.085	5.3723 (0.6393, 45.1433) /0.122	
Deep vein thrombosis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypertensive crisis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orthostatic hypotension						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Phlebitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Varicophlebitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Varicose vein						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Venous thrombosis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
White	6/214 (3%)	5/207 (2%)	1.1654 (0.3501, 3.8789) /0.803	0.3883 (-2.6557, 3.4323) /0.803	1.1607 (0.3598, 3.7449) /0.803	0.124
Non-White	6/ 94 (6%)	1/101 (<1%)	6.8182 (0.8052, 57.7366) /0.078	5.3929 (0.0874, 10.6984) /0.046	6.4468 (0.7908, 52.5555) /0.082	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.951
Non-White	2/ 94 (2%)	1/101 (<1%)	2.1739 (0.1939, 24.3767) /0.529	1.1376 (-2.3608, 4.6359) /0.524	2.1489 (0.1981, 23.3113) /0.529	
Pollakiuria						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.290
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal colic						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Haematuria						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.089
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Renal impairment						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.089
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic kidney disease						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Micturition urgency						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral discharge						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
White	5/214 (2%)	7/207 (3%)	0.6835 (0.2134, 2.1889) /0.522	-1.0452 (-4.2326, 2.1422) /0.520	0.6909 (0.2228, 2.1423) /0.522	0.973
Non-White	2/ 94 (2%)	3/101 (3%)	0.7101 (0.1160, 4.3466) /0.711	-0.8426 (-5.2553, 3.5700) /0.708	0.7163 (0.1224, 4.1928) /0.711	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Conjunctivitis allergic						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Eye pruritus						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.089
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Eyelid oedema						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Vision blurred						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Cataract						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cataract subcapsular						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Conjunctival haemorrhage						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry eye						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Eye pain						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye swelling						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Lacrimation increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ocular hyperaemia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Vitreous haematoma						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	8/214 (4%)	5/207 (2%)	1.5689 (0.5048, 4.8767) /0.436	1.3229 (-1.9686, 4.6144) /0.431	1.5477 (0.5147, 4.6536) /0.437	0.416
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
White	3/214 (1%)	2/207 (<1%)	1.4573 (0.2410, 8.8119) /0.682	0.4357 (-1.6275, 2.4989) /0.679	1.4509 (0.2449, 8.5949) /0.682	0.858
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Lipoma						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Basal cell carcinoma						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Fibrous histiocytoma						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Knuckle pads						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Melanocytic naevus						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Papillary thyroid cancer						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Seminoma						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin papilloma						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Squamous cell carcinoma						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Squamous cell carcinoma of skin						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
White	6/214 (3%)	2/207 (<1%)	2.9567 (0.5899, 14.8199) /0.187	1.8376 (-0.7446, 4.4197) /0.163	2.9019 (0.5924, 14.2138) /0.189	0.443
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.089
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vertigo						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deafness						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Ear discomfort						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Excessive cerumen production						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
White	5/214 (2%)	1/207 (<1%)	4.9282 (0.5708, 42.5474) /0.147	1.8534 (-0.3801, 4.0868) /0.104	4.8364 (0.5699, 41.0460) /0.149	0.395
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.958
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Allergy to animal						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Drug hypersensitivity						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Mycotic allergy						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
White	4/214 (2%)	1/207 (<1%)	3.9238 (0.4349, 35.4025) /0.223	1.3861 (-0.6596, 3.4317) /0.184	3.8692 (0.4361, 34.3292) /0.224	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Bradycardia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiovascular disorder						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Palpitations						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus tachycardia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Ventricular extrasystoles						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.202
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidism						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Hypogonadism						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thyroid mass						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Biliary tract disorder						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cholecystitis acute						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Hyperbilirubinaemia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abortion missed						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Abortion spontaneous						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Social circumstances						
Any Event						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menopause						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Stress at work						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Surgical and medical procedures						
Any Event						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Dental implantation						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	90/ 93 (97%)	74/107 (69%)	13.3784 (3.9447, 45.3724) /<.001	27.6153 (18.1564, 37.0742) /<.001	1.3993 (1.2264, 1.5965) /<.001	0.571
Europe	141/145 (97%)	106/146 (73%)	13.3019 (4.6166, 38.3269) /<.001	24.6386 (16.9287, 32.3486) /<.001	1.3394 (1.2079, 1.4852) /<.001	
Rest of World	63/ 70 (90%)	40/ 55 (73%)	3.3750 (1.2657, 8.9994) /0.015	17.2727 (3.5641, 30.9813) /0.014	1.2375 (1.0340, 1.4811) /0.020	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	51/ 93 (55%)	52/107 (49%)	1.2843 (0.7357, 2.2422) /0.379	6.2406 (-7.6151, 20.0963) /0.377	1.1284 (0.8629, 1.4757) /0.377	0.894
Europe	97/145 (67%)	86/146 (59%)	1.4099 (0.8743, 2.2735) /0.159	7.9924 (-3.0692, 19.0541) /0.157	1.1357 (0.9511, 1.3561) /0.160	
Rest of World	41/ 70 (59%)	26/ 55 (47%)	1.5769 (0.7740, 3.2126) /0.210	11.2987 (-6.2300, 28.8274) /0.206	1.2390 (0.8804, 1.7436) /0.219	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
North America	7/ 93 (8%)	10/107 (9%)	0.7895 (0.2880, 2.1646) /0.646	-1.8189 (-9.5109, 5.8731) /0.643	0.8054 (0.3193, 2.0312) /0.647	0.570
Europe	37/145 (26%)	28/146 (19%)	1.4438 (0.8280, 2.5175) /0.195	6.3392 (-3.2073, 15.8856) /0.193	1.3305 (0.8622, 2.0532) /0.197	
Rest of World	8/ 70 (11%)	4/ 55 (7%)	1.6452 (0.4685, 5.7774) /0.437	4.1558 (-5.9759, 14.2876) /0.421	1.5714 (0.4990, 4.9485) /0.440	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
North America	17/ 93 (18%)	11/107 (10%)	1.9522 (0.8633, 4.4144) /0.108	7.9992 (-1.7382, 17.7366) /0.107	1.7781 (0.8780, 3.6011) /0.110	0.401
Europe	4/145 (3%)	5/146 (3%)	0.8000 (0.2105, 3.0410) /0.743	-0.6660 (-4.6421, 3.3100) /0.743	0.8055 (0.2207, 2.9396) /0.743	
Rest of World	11/ 70 (16%)	9/ 55 (16%)	0.9529 (0.3643, 2.4927) /0.922	-0.6494 (-13.6214, 12.3227) /0.922	0.9603 (0.4285, 2.1523) /0.922	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza North America	3/ 93 (3%)	3/107 (3%)	1.1556 (0.2275, 5.8683) /0.862	0.4221 (-4.3401, 5.1842) /0.862	1.1505 (0.2379, 5.5635) /0.862	0.997
Europe	11/145 (8%)	9/146 (6%)	1.2496 (0.5017, 3.1123) /0.632	1.4218 (-4.3913, 7.2350) /0.632	1.2307 (0.5258, 2.8806) /0.632	
Rest of World	3/ 70 (4%)	2/ 55 (4%)	1.1866 (0.1913, 7.3609) /0.854	0.6494 (-6.2053, 7.5040) /0.853	1.1786 (0.2040, 6.8093) /0.854	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	0.390
Europe	10/145 (7%)	14/146 (10%)	0.6984 (0.2996, 1.6279) /0.406	-2.6925 (-9.0029, 3.6179) /0.403	0.7192 (0.3303, 1.5663) /0.407	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis North America	4/ 93 (4%)	5/107 (5%)	0.9169 (0.2388, 3.5197) /0.899	-0.3718 (-6.1159, 5.3722) /0.899	0.9204 (0.2546, 3.3273) /0.899	0.949
Europe	6/145 (4%)	5/146 (3%)	1.2173 (0.3631, 4.0809) /0.750	0.7133 (-3.6698, 5.0963) /0.750	1.2083 (0.3771, 3.8711) /0.750	
Rest of World	3/ 70 (4%)	2/ 55 (4%)	1.1866 (0.1913, 7.3609) /0.854	0.6494 (-6.2053, 7.5040) /0.853	1.1786 (0.2040, 6.8093) /0.854	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
North America	0/ 93	0/107	NC	NC	NC	0.999
Europe	9/145 (6%)	11/146 (8%)	0.8122 (0.3261, 2.0228) /0.655	-1.3274 (-7.1371, 4.4824) /0.654	0.8238 (0.3520, 1.9283) /0.655	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis North America	3/ 93 (3%)	4/107 (4%)	0.8583 (0.1871, 3.9380) /0.844	-0.5125 (-5.5933, 4.5682) /0.843	0.8629 (0.1982, 3.7565) /0.844	0.854
Europe	4/145 (3%)	6/146 (4%)	0.6619 (0.1828, 2.3965) /0.530	-1.3510 (-5.5313, 2.8294) /0.526	0.6713 (0.1935, 2.3292) /0.530	
Rest of World	1/ 70 (1%)	2/ 55 (4%)	0.3841 (0.0339, 4.3494) /0.440	-2.2078 (-7.8825, 3.4669) /0.446	0.3929 (0.0366, 4.2208) /0.441	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
North America	7/ 93 (8%)	3/107 (3%)	2.8217 (0.7082, 11.2423) /0.141	4.7231 (-1.4844, 10.9307) /0.136	2.6846 (0.7145, 10.0863) /0.144	0.283
Europe	0/145	0/146	NC	NC	NC	
Rest of World	4/ 70 (6%)	5/ 55 (9%)	0.6061 (0.1547, 2.3736) /0.472	-3.3766 (-12.7195, 5.9663) /0.479	0.6286 (0.1771, 2.2304) /0.472	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
North America	3/ 93 (3%)	3/107 (3%)	1.1556 (0.2275, 5.8683) /0.862	0.4221 (-4.3401, 5.1842) /0.862	1.1505 (0.2379, 5.5635) /0.862	0.291
Europe	1/145 (<1%)	6/146 (4%)	0.1620 (0.0193, 1.3632) /0.094	-3.4199 (-6.9104, 0.0705) /0.055	0.1678 (0.0205, 1.3766) /0.096	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis North America	2/ 93 (2%)	3/107 (3%)	0.7619 (0.1245, 4.6611) /0.769	-0.6532 (-4.9515, 3.6451) /0.766	0.7670 (0.1310, 4.4918) /0.769	0.407
Europe	5/145 (3%)	2/146 (1%)	2.5714 (0.4908, 13.4732) /0.264	2.0784 (-1.4395, 5.5963) /0.247	2.5172 (0.4963, 12.7663) /0.265	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis North America	2/ 93 (2%)	4/107 (4%)	0.5659 (0.1013, 3.1625) /0.517	-1.5878 (-6.2366, 3.0610) /0.503	0.5753 (0.1078, 3.0696) /0.518	0.956
Europe	2/145 (1%)	5/146 (3%)	0.3944 (0.0753, 2.0665) /0.271	-2.0453 (-5.5533, 1.4626) /0.253	0.4028 (0.0794, 2.0426) /0.272	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.902
Europe	7/145 (5%)	3/146 (2%)	2.4179 (0.6128, 9.5397) /0.207	2.7728 (-1.4066, 6.9522) /0.193	2.3494 (0.6196, 8.9085) /0.209	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	6/ 70 (9%)	5/ 55 (9%)	0.9375 (0.2704, 3.2498) /0.919	-0.5195 (-10.5559, 9.5169) /0.919	0.9429 (0.3036, 2.9277) /0.919	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
North America	3/ 93 (3%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	4/145 (3%)	3/146 (2%)	1.3522 (0.2973, 6.1514) /0.696	0.7038 (-2.8178, 4.2255) /0.695	1.3425 (0.3059, 5.8930) /0.696	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
North America	3/ 93 (3%)	3/107 (3%)	1.1556 (0.2275, 5.8683) /0.862	0.4221 (-4.3401, 5.1842) /0.862	1.1505 (0.2379, 5.5635) /0.862	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	0.061
Europe	2/145 (1%)	5/146 (3%)	0.3944 (0.0753, 2.0665) /0.271	-2.0453 (-5.5533, 1.4626) /0.253	0.4028 (0.0794, 2.0426) /0.272	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	0.680
Europe	3/145 (2%)	2/146 (1%)	1.5211 (0.2504, 9.2405) /0.649	0.6991 (-2.2880, 3.6862) /0.646	1.5103 (0.2561, 8.9059) /0.649	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	3/145 (2%)	4/146 (3%)	0.7500 (0.1649, 3.4118) /0.710	-0.6708 (-4.1891, 2.8476) /0.709	0.7552 (0.1720, 3.3148) /0.710	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	0.346
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	4/ 70 (6%)	1/ 55 (2%)	3.2727 (0.3552, 30.1518) /0.295	3.8961 (-2.5873, 10.3795) /0.239	3.1429 (0.3615, 27.3248) /0.299	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	0.077
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	0.663
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute sinusitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.490
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle North America	3/ 93 (3%)	1/107 (<1%)	3.5333 (0.3612, 34.5630) /0.278	2.2912 (-1.7360, 6.3185) /0.265	3.4516 (0.3652, 32.6189) /0.280	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	0.300
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.998
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Onychomycosis						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea versicolour						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth infection						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.474
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Candida infection						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site abscess						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea cruris						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	3/146 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3290 (-21.2640, 12.6059) /0.616	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal infection						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic tonsillitis						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	2/146 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6449 (-20.6173, 13.3275) /0.674	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal infection						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impetigo North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site cellulitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media acute						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	2/146 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6449 (-20.6173, 13.3275) /0.674	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pulpitis dental						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal infection						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth abscess						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis chlamydial						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis C						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amoebiasis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal human papilloma virus infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Appendicitis North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervicitis human papilloma virus						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Clostridium difficile colitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis bacterial						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis infectious						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epididymitis North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Folliculitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastric infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal viral infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival abscess						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Groin abscess						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes virus infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infected bite						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection parasitic						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver abscess						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Localised infection						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal herpes						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral candidiasis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Periodontitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pertussis North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia mycoplasmal						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Primary syphilis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis chlamydial						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis herpes						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis acute						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotavirus infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted disease						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin candida						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea infection						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea pedis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue fungal infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ureaplasma infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral tonsillitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal candidiasis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginitis trichomonal						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
North America	75/ 93 (81%)	7/107 (7%)	59.5238 (23.6516, 149.8031) /<.001	74.1031 (64.8067, 83.3996) /<.001	12.3272 (5.9821, 25.4026) /<.001	NC
Europe	125/145 (86%)	10/146 (7%)	85.0000 (38.3080, 188.6028) /<.001	79.3576 (72.4086, 86.3066) /<.001	12.5862 (6.8955, 22.9732) /<.001	
Rest of World	52/ 70 (74%)	5/ 55 (9%)	28.8888 (9.9673, 83.7302) /<.001	65.1948 (52.4453, 77.9444) /<.001	8.1714 (3.5030, 19.0614) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain North America	62/ 93 (67%)	0/107	>999 (>999, >999) /NC	NC	NC	NC
Europe	118/145 (81%)	0/146	>999 (>999, >999) /NC	NC	NC	
Rest of World	51/ 70 (73%)	0/ 55	>999 (>999, >999) /NC	71.7420 (43.2395, 100.2444) /<.001	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
North America	16/ 93 (17%)	0/107	>999 (>999, >999) /NC	18.7993 (-1.8518, 39.4503) /0.074	>999 (>999, >999) /NC	NC
Europe	12/145 (8%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	9/ 70 (13%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
North America	7/ 93 (8%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	20/145 (14%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	3/ 70 (4%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia North America	4/ 93 (4%)	4/107 (4%)	1.1573 (0.2812, 4.7623) /0.840	0.5628 (-4.9073, 6.0328) /0.840	1.1505 (0.2960, 4.4727) /0.840	0.293
Europe	15/145 (10%)	5/146 (3%)	3.2538 (1.1503, 9.2040) /0.026	6.9202 (1.1519, 12.6885) /0.019	3.0207 (1.1273, 8.0944) /0.028	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue North America	9/ 93 (10%)	3/107 (3%)	3.7143 (0.9746, 14.1553) /0.055	6.8737 (0.0996, 13.6478) /0.047	3.4516 (0.9628, 12.3740) /0.057	0.817
Europe	12/145 (8%)	3/146 (2%)	4.3008 (1.1874, 15.5768) /0.026	6.2211 (1.1806, 11.2615) /0.016	4.0276 (1.1607, 13.9751) /0.028	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
North America	8/ 93 (9%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	11/145 (8%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	4/ 70 (6%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.737
Europe	6/145 (4%)	2/146 (1%)	3.1079 (0.6168, 15.6603) /0.169	2.7681 (-0.9821, 6.5182) /0.148	3.0207 (0.6199, 14.7200) /0.171	
Rest of World	4/ 70 (6%)	1/ 55 (2%)	3.2727 (0.3552, 30.1518) /0.295	3.8961 (-2.5873, 10.3795) /0.239	3.1429 (0.3615, 27.3248) /0.299	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	10/145 (7%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site bruising						
North America	7/ 93 (8%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	3/ 70 (4%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain						
North America	4/ 93 (4%)	1/107 (<1%)	4.7640 (0.5230, 43.3995) /0.166	3.3665 (-1.1419, 7.8749) /0.143	4.6022 (0.5236, 40.4530) /0.169	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
North America	6/ 93 (6%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haematoma						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	5/145 (3%)	0/146	>999 (>999, >999) /NC	5.6819 (-11.2187, 22.5824) /0.510	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	6/145 (4%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia North America	0/ 93	0/107	NC	NC	NC	NC
Europe	5/145 (3%)	0/146	>999 (>999, >999) /NC	5.6819 (-11.2187, 22.5824) /0.510	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site warmth						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	3/ 70 (4%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site reaction						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cyst						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Discomfort North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oedema peripheral						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest discomfort						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling of body temperature change						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site anaesthesia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral swelling						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vessel puncture site pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	29/ 93 (31%)	16/107 (15%)	2.5771 (1.2939, 5.1332) /0.007	16.2295 (4.6409, 27.8181) /0.006	2.0853 (1.2110, 3.5909) /0.008	0.082
Europe	25/145 (17%)	24/146 (16%)	1.0590 (0.5730, 1.9572) /0.855	0.8030 (-7.7960, 9.4021) /0.855	1.0489 (0.6293, 1.7480) /0.855	
Rest of World	20/ 70 (29%)	6/ 55 (11%)	3.2667 (1.2093, 8.8244) /0.020	17.6623 (4.2505, 31.0742) /0.010	2.6190 (1.1293, 6.0739) /0.025	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
North America	10/ 93 (11%)	7/107 (7%)	1.7212 (0.6277, 4.7199) /0.291	4.2106 (-3.6373, 12.0585) /0.293	1.6436 (0.6517, 4.1452) /0.292	0.450
Europe	7/145 (5%)	7/146 (5%)	1.0072 (0.3442, 2.9477) /0.989	0.0331 (-4.8845, 4.9506) /0.989	1.0069 (0.3623, 2.7983) /0.989	
Rest of World	5/ 70 (7%)	1/ 55 (2%)	4.1538 (0.4709, 36.6416) /0.200	5.3247 (-1.6658, 12.3152) /0.135	3.9286 (0.4726, 32.6572) /0.205	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea North America	7/ 93 (8%)	4/107 (4%)	2.0959 (0.5937, 7.3993) /0.250	3.7886 (-2.6667, 10.2438) /0.250	2.0134 (0.6085, 6.6624) /0.252	0.342
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	4/ 70 (6%)	1/ 55 (2%)	3.2727 (0.3552, 30.1518) /0.295	3.8961 (-2.5873, 10.3795) /0.239	3.1429 (0.3615, 27.3248) /0.299	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache North America	3/ 93 (3%)	2/107 (2%)	1.7500 (0.2860, 10.7062) /0.545	1.3566 (-3.0569, 5.7702) /0.547	1.7258 (0.2947, 10.1065) /0.545	0.337
Europe	2/145 (1%)	3/146 (2%)	0.6667 (0.1097, 4.0499) /0.660	-0.6755 (-3.6586, 2.3077) /0.657	0.6713 (0.1138, 3.9582) /0.660	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting North America	4/ 93 (4%)	4/107 (4%)	1.1573 (0.2812, 4.7623) /0.840	0.5628 (-4.9073, 6.0328) /0.840	1.1505 (0.2960, 4.4727) /0.840	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation						
North America	2/ 93 (2%)	2/107 (2%)	1.1538 (0.1593, 8.3567) /0.887	0.2814 (-3.6272, 4.1900) /0.888	1.1505 (0.1653, 8.0076) /0.887	0.118
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
North America	4/ 93 (4%)	2/107 (2%)	2.3595 (0.4222, 13.1863) /0.328	2.4319 (-2.4247, 7.2886) /0.326	2.3011 (0.4312, 12.2786) /0.329	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	3/ 70 (4%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.557
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	2/ 70 (3%)	1/ 55 (2%)	1.5882 (0.1403, 17.9846) /0.709	1.0390 (-4.2241, 6.3020) /0.699	1.5714 (0.1463, 16.8832) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aphthous ulcer						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental caries						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	2/146 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6449 (-20.6173, 13.3275) /0.674	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal distension						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal hernia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal pruritus						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal skin tags						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal discomfort						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic gastritis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphagia North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilic oesophagitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epigastric discomfort						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Functional gastrointestinal disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival disorder						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids thrombosed						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritable bowel syndrome						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip dry North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip swelling						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mouth ulceration						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral disorder						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral pain						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis acute						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis chronic						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis ulcerative						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Steatorrhoea						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue ulceration						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth impacted						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Umbilical hernia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	22/ 93 (24%)	16/107 (15%)	1.7623 (0.8622, 3.6020) /0.120	8.7026 (-2.2634, 19.6687) /0.120	1.5820 (0.8849, 2.8282) /0.122	0.402
Europe	37/145 (26%)	19/146 (13%)	2.2900 (1.2445, 4.2136) /0.008	12.5035 (3.5516, 21.4555) /0.006	1.9608 (1.1855, 3.2431) /0.009	
Rest of World	10/ 70 (14%)	8/ 55 (15%)	0.9792 (0.3584, 2.6751) /0.967	-0.2597 (-12.6699, 12.1504) /0.967	0.9821 (0.4156, 2.3210) /0.967	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain North America	6/ 93 (6%)	4/107 (4%)	1.7759 (0.4855, 6.4962) /0.385	2.7133 (-3.4389, 8.8655) /0.387	1.7258 (0.5023, 5.9296) /0.386	0.254
Europe	11/145 (8%)	6/146 (4%)	1.9154 (0.6889, 5.3253) /0.213	3.4766 (-1.9031, 8.8564) /0.205	1.8460 (0.7013, 4.8589) /0.214	
Rest of World	4/ 70 (6%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
North America	3/ 93 (3%)	3/107 (3%)	1.1556 (0.2275, 5.8683) /0.862	0.4221 (-4.3401, 5.1842) /0.862	1.1505 (0.2379, 5.5635) /0.862	0.445
Europe	3/145 (2%)	4/146 (3%)	0.7500 (0.1649, 3.4118) /0.710	-0.6708 (-4.1891, 2.8476) /0.709	0.7552 (0.1720, 3.3148) /0.710	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
North America	2/ 93 (2%)	4/107 (4%)	0.5659 (0.1013, 3.1625) /0.517	-1.5878 (-6.2366, 3.0610) /0.503	0.5753 (0.1078, 3.0696) /0.518	0.260
Europe	3/145 (2%)	3/146 (2%)	1.0070 (0.1999, 5.0737) /0.993	0.0142 (-3.2513, 3.2796) /0.993	1.0069 (0.2066, 4.9067) /0.993	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
North America	1/ 93 (1%)	6/107 (6%)	0.1830 (0.0216, 1.5486) /0.119	-4.5322 (-9.3692, 0.3048) /0.066	0.1918 (0.0235, 1.5639) /0.123	0.129
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	3/ 70 (4%)	1/ 55 (2%)	2.4179 (0.2445, 23.9097) /0.450	2.4675 (-3.4468, 8.3819) /0.414	2.3571 (0.2521, 22.0408) /0.452	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia North America	3/ 93 (3%)	1/107 (<1%)	3.5333 (0.3612, 34.5630) /0.278	2.2912 (-1.7360, 6.3185) /0.265	3.4516 (0.3652, 32.6189) /0.280	0.098
Europe	5/145 (3%)	0/146	>999 (>999, >999) /NC	5.6819 (-11.2187, 22.5824) /0.510	>999 (>999, >999) /NC	
Rest of World	2/ 70 (3%)	2/ 55 (4%)	0.7794 (0.1063, 5.7166) /0.806	-0.7792 (-7.0805, 5.5220) /0.808	0.7857 (0.1143, 5.4017) /0.806	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
North America	1/ 93 (1%)	3/107 (3%)	0.3768 (0.0385, 3.6858) /0.402	-1.7285 (-5.4938, 2.0368) /0.368	0.3835 (0.0406, 3.6243) /0.403	0.196
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain North America	3/ 93 (3%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteoarthritis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.203
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	4/145 (3%)	0/146	>999 (>999, >999) /NC	5.0157 (-11.8696, 21.9009) /0.560	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint swelling						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropathy North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bursitis North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot deformity						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc protrusion						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteopenia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Costochondritis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dupuytren's contracture						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exostosis North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flank pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint effusion						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle tightness						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myositis North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteonecrosi s						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Patellofemoral pain syndrome						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Polyarthriti s						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhabdomyolysis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scoliosis North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal osteoarthritis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovial cyst						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temporomandibular joint syndrome						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tenosynovitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
North America	19/ 93 (20%)	14/107 (13%)	1.7056 (0.8018, 3.6283) /0.166	7.3460 (-3.0451, 17.7371) /0.166	1.5614 (0.8300, 2.9375) /0.167	0.750
Europe	32/145 (22%)	15/146 (10%)	2.4732 (1.2745, 4.7990) /0.007	11.7950 (3.4392, 20.1508) /0.006	2.1480 (1.2164, 3.7931) /0.008	
Rest of World	13/ 70 (19%)	6/ 55 (11%)	1.8626 (0.6584, 5.2694) /0.241	7.6623 (-4.6206, 19.9453) /0.221	1.7024 (0.6917, 4.1895) /0.247	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
North America	7/ 93 (8%)	6/107 (6%)	1.3702 (0.4436, 4.2318) /0.584	1.9194 (-4.9910, 8.8298) /0.586	1.3423 (0.4676, 3.8528) /0.584	0.335
Europe	19/145 (13%)	10/146 (7%)	2.0508 (0.9186, 4.5786) /0.080	6.2541 (-0.5981, 13.1064) /0.074	1.9131 (0.9215, 3.9715) /0.082	
Rest of World	8/ 70 (11%)	1/ 55 (2%)	6.9677 (0.8442, 57.5075) /0.071	9.6104 (1.3631, 17.8577) /0.022	6.2857 (0.8103, 48.7604) /0.079	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness						
North America	4/ 93 (4%)	1/107 (<1%)	4.7640 (0.5230, 43.3995) /0.166	3.3665 (-1.1419, 7.8749) /0.143	4.6022 (0.5236, 40.4530) /0.169	0.276
Europe	4/145 (3%)	2/146 (1%)	2.0426 (0.3683, 11.3293) /0.414	1.3888 (-1.8765, 4.6540) /0.405	2.0138 (0.3747, 10.8241) /0.415	
Rest of World	1/ 70 (1%)	2/ 55 (4%)	0.3841 (0.0339, 4.3494) /0.440	-2.2078 (-7.8825, 3.4669) /0.446	0.3929 (0.0366, 4.2208) /0.441	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica North America	4/ 93 (4%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	3/145 (2%)	1/146 (<1%)	3.0634 (0.3149, 29.7994) /0.335	1.3840 (-1.2913, 4.0594) /0.311	3.0207 (0.3179, 28.7018) /0.336	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia						
North America	3/ 93 (3%)	2/107 (2%)	1.7500 (0.2860, 10.7062) /0.545	1.3566 (-3.0569, 5.7702) /0.547	1.7258 (0.2947, 10.1065) /0.545	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervicobrachial syndrome						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuralgia						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syncope North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia ^a						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Somnolence North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anterograde amnesia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Autonomic nervous system imbalance						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Burning sensation						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebral cyst						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebrovascular accident						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cognitive disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Disturbance in attention						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysaesthesia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysgeusia North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dystonia North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Essential tremor						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Facial paralysis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intercostal neuralgia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Loss of consciousness						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Memory impairment						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contractions involuntary						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuromuscular blockade						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post herpetic neuralgia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post-traumatic headache						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seizure North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension headache						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	15/ 93 (16%)	20/107 (19%)	0.8365 (0.4008, 1.7462) /0.635	-2.5626 (-13.0716, 7.9465) /0.633	0.8629 (0.4693, 1.5866) /0.635	0.578
Europe	13/145 (9%)	9/146 (6%)	1.4992 (0.6200, 3.6247) /0.369	2.8011 (-3.2686, 8.8709) /0.366	1.4544 (0.6417, 3.2964) /0.370	
Rest of World	8/ 70 (11%)	7/ 55 (13%)	0.8848 (0.2998, 2.6109) /0.825	-1.2987 (-12.8369, 10.2395) /0.825	0.8980 (0.3470, 2.3240) /0.824	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough North America	5/ 93 (5%)	10/107 (9%)	0.5511 (0.1813, 1.6751) /0.294	-3.9695 (-11.1410, 3.2021) /0.278	0.5753 (0.2040, 1.6226) /0.296	0.140
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	7/ 70 (10%)	3/ 55 (5%)	1.9259 (0.4742, 7.8215) /0.359	4.5455 (-4.6963, 13.7872) /0.335	1.8333 (0.4969, 6.7647) /0.363	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
North America	5/ 93 (5%)	5/107 (5%)	1.1591 (0.3249, 4.1355) /0.820	0.7034 (-5.3798, 6.7867) /0.821	1.1505 (0.3438, 3.8508) /0.820	0.727
Europe	2/145 (1%)	4/146 (3%)	0.4965 (0.0895, 2.7539) /0.423	-1.3604 (-4.6185, 1.8976) /0.413	0.5034 (0.0937, 2.7060) /0.424	
Rest of World	2/ 70 (3%)	2/ 55 (4%)	0.7794 (0.1063, 5.7166) /0.806	-0.7792 (-7.0805, 5.5220) /0.808	0.7857 (0.1143, 5.4017) /0.806	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
North America	1/ 93 (1%)	4/107 (4%)	0.2799 (0.0307, 2.5495) /0.259	-2.6630 (-6.8240, 1.4979) /0.210	0.2876 (0.0327, 2.5283) /0.261	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus congestion						
North America	4/ 93 (4%)	2/107 (2%)	2.3595 (0.4222, 13.1863) /0.328	2.4319 (-2.4247, 7.2886) /0.326	2.3011 (0.4312, 12.2786) /0.329	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory disorder						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphonia North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract congestion						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspnoea North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Productive cough						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract congestion						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchospasm North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Emphysema North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lung disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal obstruction						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal septum deviation						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pulmonary mass						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Reflux laryngitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory distress						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep apnoea syndrome						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wheezing North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	14/ 93 (15%)	18/107 (17%)	0.8762 (0.4092, 1.8761) /0.734	-1.7687 (-11.9203, 8.3830) /0.733	0.8949 (0.4715, 1.6984) /0.734	0.007
Europe	18/145 (12%)	5/146 (3%)	3.9969 (1.4421, 11.0775) /0.008	8.9891 (2.8648, 15.1134) /0.004	3.6248 (1.3827, 9.5029) /0.009	
Rest of World	5/ 70 (7%)	8/ 55 (15%)	0.4519 (0.1390, 1.4688) /0.187	-7.4026 (-18.5028, 3.6976) /0.191	0.4911 (0.1701, 1.4175) /0.189	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
North America	3/ 93 (3%)	2/107 (2%)	1.7500 (0.2860, 10.7062) /0.545	1.3566 (-3.0569, 5.7702) /0.547	1.7258 (0.2947, 10.1065) /0.545	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
North America	2/ 93 (2%)	3/107 (3%)	0.7619 (0.1245, 4.6611) /0.769	-0.6532 (-4.9515, 3.6451) /0.766	0.7670 (0.1310, 4.4918) /0.769	0.593
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.074
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	0.905
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Procedural pain						
North America	1/ 93 (1%)	3/107 (3%)	0.3768 (0.0385, 3.6858) /0.402	-1.7285 (-5.4938, 2.0368) /0.368	0.3835 (0.0406, 3.6243) /0.403	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epicondylitis						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exposure to communicable disease						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Road traffic accident						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bone contusion						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection related reaction						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Radius fracture						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Soft tissue injury						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper limb fracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Buttock injury						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye injury						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Facial bones fracture						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Humerus fracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury corneal						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint dislocation						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament rupture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Meniscus injury						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural complication						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin abrasion						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin injury						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Splinter North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon rupture						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth fracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	11/ 93 (12%)	9/107 (8%)	1.4607 (0.5772, 3.6966) /0.424	3.4167 (-4.9937, 11.8272) /0.426	1.4062 (0.6095, 3.2442) /0.424	0.711
Europe	21/145 (14%)	11/146 (8%)	2.0784 (0.9632, 4.4851) /0.062	6.9485 (-0.2029, 14.0999) /0.057	1.9223 (0.9619, 3.8414) /0.064	
Rest of World	4/ 70 (6%)	3/ 55 (5%)	1.0505 (0.2251, 4.9023) /0.950	0.2597 (-7.8388, 8.3583) /0.950	1.0476 (0.2446, 4.4871) /0.950	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	0.111
Europe	5/145 (3%)	1/146 (<1%)	5.1786 (0.5975, 44.8841) /0.136	2.7633 (-0.4940, 6.0207) /0.096	5.0345 (0.5955, 42.5641) /0.138	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.331
Europe	3/145 (2%)	3/146 (2%)	1.0070 (0.1999, 5.0737) /0.993	0.0142 (-3.2513, 3.2796) /0.993	1.0069 (0.2066, 4.9067) /0.993	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	0.944
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	3/145 (2%)	1/146 (<1%)	3.0634 (0.3149, 29.7994) /0.335	1.3840 (-1.2913, 4.0594) /0.311	3.0207 (0.3179, 28.7018) /0.336	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood pressure increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	4/146 (3%)	<0.0001 (<0.0001, -) />0.999	-4.9973 (-21.9315, 11.9368) /0.563	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	4/145 (3%)	0/146	>999 (>999, >999) /NC	5.0157 (-11.8696, 21.9009) /0.560	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine decreased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	2/146 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6449 (-20.6173, 13.3275) /0.674	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	3/146 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3290 (-21.2640, 12.6059) /0.616	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood phosphorus decreased						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	2/146 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6449 (-20.6173, 13.3275) /0.674	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Activated partial thromboplastin time prolonged						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
ECG signs of ventricular hypertrophy						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glycosylated haemoglobin increased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic enzyme increased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipids increased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neisseria test positive						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatic enzymes increased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thyroxine free decreased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight increased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
North America	11/ 93 (12%)	8/107 (7%)	1.6601 (0.6378, 4.3208) /0.299	4.3513 (-3.8896, 12.5923) /0.301	1.5820 (0.6646, 3.7659) /0.300	0.925
Europe	15/145 (10%)	10/146 (7%)	1.5692 (0.6805, 3.6185) /0.290	3.4955 (-2.9355, 9.9266) /0.287	1.5103 (0.7018, 3.2504) /0.292	
Rest of World	10/ 70 (14%)	4/ 55 (7%)	2.1250 (0.6285, 7.1844) /0.225	7.0130 (-3.6781, 17.7041) /0.199	1.9643 (0.6510, 5.9273) /0.231	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
North America	4/ 93 (4%)	2/107 (2%)	2.3595 (0.4222, 13.1863) /0.328	2.4319 (-2.4247, 7.2886) /0.326	2.3011 (0.4312, 12.2786) /0.329	0.969
Europe	3/145 (2%)	1/146 (<1%)	3.0634 (0.3149, 29.7994) /0.335	1.3840 (-1.2913, 4.0594) /0.311	3.0207 (0.3179, 28.7018) /0.336	
Rest of World	4/ 70 (6%)	1/ 55 (2%)	3.2727 (0.3552, 30.1518) /0.295	3.8961 (-2.5873, 10.3795) /0.239	3.1429 (0.3615, 27.3248) /0.299	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	0.403
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acne						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.474
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash pruritic						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alopecia North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash generalised						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoeic dermatitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ecchymosis						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urticaria						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decubitus ulcer						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Dermatitis acneiform						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis contact						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intertrigo North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nail bed bleeding						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neurodermatitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychoclasia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Photosensitivity reaction						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus generalised						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Purpura North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash erythematous						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash maculo-papular						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sebacious hyperplasia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoea North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin fissures						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin lesion						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin mass						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stasis dermatitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
North America	15/ 93 (16%)	13/107 (12%)	1.3905 (0.6241, 3.0980) /0.420	3.9795 (-5.7260, 13.6850) /0.422	1.3275 (0.6667, 2.6435) /0.420	0.132
Europe	9/145 (6%)	10/146 (7%)	0.9000 (0.3546, 2.2842) /0.825	-0.6424 (-6.3178, 5.0330) /0.824	0.9062 (0.3794, 2.1646) /0.825	
Rest of World	8/ 70 (11%)	1/ 55 (2%)	6.9677 (0.8442, 57.5075) /0.071	9.6104 (1.3631, 17.8577) /0.022	6.2857 (0.8103, 48.7604) /0.079	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia North America	8/ 93 (9%)	3/107 (3%)	3.2627 (0.8395, 12.6805) /0.088	5.7984 (-0.7023, 12.2991) /0.080	3.0681 (0.8383, 11.2295) /0.090	0.437
Europe	3/145 (2%)	1/146 (<1%)	3.0634 (0.3149, 29.7994) /0.335	1.3840 (-1.2913, 4.0594) /0.311	3.0207 (0.3179, 28.7018) /0.336	
Rest of World	4/ 70 (6%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety						
North America	6/ 93 (6%)	3/107 (3%)	2.3908 (0.5809, 9.8403) /0.227	3.6479 (-2.2439, 9.5397) /0.225	2.3011 (0.5919, 8.9454) /0.229	0.363
Europe	2/145 (1%)	4/146 (3%)	0.4965 (0.0895, 2.7539) /0.423	-1.3604 (-4.6185, 1.8976) /0.413	0.5034 (0.0937, 2.7060) /0.424	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression North America	2/ 93 (2%)	5/107 (5%)	0.4484 (0.0849, 2.3675) /0.345	-2.5224 (-7.4907, 2.4460) /0.320	0.4602 (0.0914, 2.3165) /0.347	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	0.905
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute stress disorder						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Affect lability						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety disorder						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression suicidal						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug dependence						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritability						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mood altered						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Mood swings						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Panic disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal behaviour						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thinking abnormal						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
North America	4/ 93 (4%)	14/107 (13%)	0.2986 (0.0947, 0.9416) /0.039	-8.7830 (-16.3876, -1.1785) /0.024	0.3287 (0.1121, 0.9640) /0.043	0.494
Europe	5/145 (3%)	6/146 (4%)	0.8333 (0.2486, 2.7938) /0.768	-0.6613 (-5.0418, 3.7192) /0.767	0.8391 (0.2619, 2.6883) /0.768	
Rest of World	5/ 70 (7%)	7/ 55 (13%)	0.5275 (0.1578, 1.7631) /0.299	-5.5844 (-16.2605, 5.0916) /0.305	0.5612 (0.1883, 1.6725) /0.300	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
North America	2/ 93 (2%)	8/107 (7%)	0.2720 (0.0563, 1.3144) /0.105	-5.3261 (-11.1164, 0.4642) /0.071	0.2876 (0.0626, 1.3209) /0.109	0.140
Europe	2/145 (1%)	3/146 (2%)	0.6667 (0.1097, 4.0499) /0.660	-0.6755 (-3.6586, 2.3077) /0.657	0.6713 (0.1138, 3.9582) /0.660	
Rest of World	4/ 70 (6%)	1/ 55 (2%)	3.2727 (0.3552, 30.1518) /0.295	3.8961 (-2.5873, 10.3795) /0.239	3.1429 (0.3615, 27.3248) /0.299	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 70 (1%)	3/ 55 (5%)	0.2512 (0.0254, 2.4847) /0.237	-4.0260 (-10.6401, 2.5882) /0.233	0.2619 (0.0280, 2.4490) /0.240	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decreased appetite						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dehydration						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gout						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperglycaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertriglyceridaemia						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypophosphat aemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Increased appetite						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetes mellitus						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic ketoacidosis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypokalaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impaired fasting glucose						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B12 deficiency						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B6 deficiency						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
North America	5/ 93 (5%)	4/107 (4%)	1.4631 (0.3811, 5.6167) /0.579	1.6380 (-4.1872, 7.4632) /0.582	1.4382 (0.3978, 5.1990) /0.579	0.478
Europe	9/145 (6%)	2/146 (1%)	4.7647 (1.0113, 22.4484) /0.048	4.8370 (0.4806, 9.1934) /0.030	4.5310 (0.9961, 20.6104) /0.051	
Rest of World	2/ 70 (3%)	1/ 55 (2%)	1.5882 (0.1403, 17.9846) /0.709	1.0390 (-4.2241, 6.3020) /0.699	1.5714 (0.1463, 16.8832) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign prostatic hyperplasia						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menorrhagia North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Balanoposthitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysmenorrhoe ^a						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenomyosis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cyst						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysfunctional uterine bleeding						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital erythema						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menometrorrhagia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menstrual disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metrorrhagia						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst ruptured						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scrotal mass North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal discharge						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal haemorrhage						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	0.506
Europe	4/145 (3%)	6/146 (4%)	0.6619 (0.1828, 2.3965) /0.530	-1.3510 (-5.5313, 2.8294) /0.526	0.6713 (0.1935, 2.3292) /0.530	
Rest of World	3/ 70 (4%)	5/ 55 (9%)	0.4478 (0.1022, 1.9620) /0.286	-4.8052 (-13.7625, 4.1522) /0.293	0.4714 (0.1178, 1.8872) /0.288	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia North America	0/ 93	0/107	NC	NC	NC	0.522
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	2/ 70 (3%)	4/ 55 (7%)	0.3750 (0.0661, 2.1275) /0.268	-4.4156 (-12.3107, 3.4796) /0.273	0.3929 (0.0747, 2.0666) /0.270	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia folate deficiency						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deficiency anaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Leukocytosis North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Microcytic anaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neutropenia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thrombocytopenia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
North America	2/ 93 (2%)	2/107 (2%)	1.1538 (0.1593, 8.3567) /0.887	0.2814 (-3.6272, 4.1900) /0.888	1.1505 (0.1653, 8.0076) /0.887	0.304
Europe	4/145 (3%)	4/146 (3%)	1.0071 (0.2470, 4.1059) /0.992	0.0189 (-3.7385, 3.7763) /0.992	1.0069 (0.2567, 3.9495) /0.992	
Rest of World	7/ 70 (10%)	1/ 55 (2%)	6.0000 (0.7155, 50.3169) /0.099	8.1818 (0.3168, 16.0468) /0.041	5.5000 (0.6973, 43.3827) /0.106	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	0.260
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	5/ 70 (7%)	1/ 55 (2%)	4.1538 (0.4709, 36.6416) /0.200	5.3247 (-1.6658, 12.3152) /0.135	3.9286 (0.4726, 32.6572) /0.205	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deep vein thrombosis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertensive crisis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orthostatic hypotension						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Phlebitis North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicophlebitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicose vein						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Venous thrombosis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
North America	1/ 93 (1%)	3/107 (3%)	0.3768 (0.0385, 3.6858) /0.402	-1.7285 (-5.4938, 2.0368) /0.368	0.3835 (0.0406, 3.6243) /0.403	0.053
Europe	6/145 (4%)	3/146 (2%)	2.0576 (0.5046, 8.3892) /0.314	2.0831 (-1.8923, 6.0586) /0.304	2.0138 (0.5134, 7.8990) /0.315	
Rest of World	5/ 70 (7%)	0/ 55	>999 (>999, >999) /NC	9.2175 (-18.2781, 36.7132) /0.511	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	0.243
Europe	3/145 (2%)	1/146 (<1%)	3.0634 (0.3149, 29.7994) /0.335	1.3840 (-1.2913, 4.0594) /0.311	3.0207 (0.3179, 28.7018) /0.336	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal colic						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal impairment						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic kidney disease						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Micturition urgency						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral discharge						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	0.742
Europe	3/145 (2%)	6/146 (4%)	0.4930 (0.1209, 2.0099) /0.324	-2.0406 (-6.0075, 1.9263) /0.313	0.5034 (0.1283, 1.9748) /0.325	
Rest of World	3/ 70 (4%)	2/ 55 (4%)	1.1866 (0.1913, 7.3609) /0.854	0.6494 (-6.2053, 7.5040) /0.853	1.1786 (0.2040, 6.8093) /0.854	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis allergic						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pruritus North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid oedema						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vision blurred						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract subcapsular						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctival haemorrhage						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry eye North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pain North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye swelling						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lacrimation increased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ocular hyperaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous haematoma						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	2/ 93 (2%)	2/107 (2%)	1.1538 (0.1593, 8.3567) /0.887	0.2814 (-3.6272, 4.1900) /0.888	1.1505 (0.1653, 8.0076) /0.887	0.415
Europe	5/145 (3%)	2/146 (1%)	2.5714 (0.4908, 13.4732) /0.264	2.0784 (-1.4395, 5.5963) /0.247	2.5172 (0.4963, 12.7663) /0.265	
Rest of World	2/ 70 (3%)	3/ 55 (5%)	0.5098 (0.0822, 3.1630) /0.469	-2.5974 (-9.7564, 4.5615) /0.477	0.5238 (0.0907, 3.0264) /0.470	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.275
Europe	3/145 (2%)	1/146 (<1%)	3.0634 (0.3149, 29.7994) /0.335	1.3840 (-1.2913, 4.0594) /0.311	3.0207 (0.3179, 28.7018) /0.336	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Basal cell carcinoma						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fibrous histiocytoma						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Knuckle pads						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Melanocytic naevus						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papillary thyroid cancer						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seminoma North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin papilloma						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Squamous cell carcinoma						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Squamous cell carcinoma of skin						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
North America	2/ 93 (2%)	2/107 (2%)	1.1538 (0.1593, 8.3567) /0.887	0.2814 (-3.6272, 4.1900) /0.888	1.1505 (0.1653, 8.0076) /0.887	NC
Europe	4/145 (3%)	0/146	>999 (>999, >999) /NC	5.0157 (-11.8696, 21.9009) /0.560	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deafness North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear discomfort						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Excessive cerumen production						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	0.267
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	0.263
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Allergy to animal						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug hypersensitivity						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycotic allergy						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bradycardia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiovascular disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Palpitations						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus tachycardia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ventricular extrasystoles						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	0.263
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidism						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypogonadism						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thyroid mass						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Biliary tract disorder						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis acute						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatocellular injury						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbilirubinaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion missed						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion spontaneous						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Social circumstances						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menopause North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress at work						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental implantation						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
PI	47/ 51 (92%)	36/ 54 (67%)	5.8750 (1.8286, 18.8752) /0.003	25.4902 (10.9119, 40.0685) /<.001	1.3824 (1.1263, 1.6967) /0.002	0.448
INI	99/102 (97%)	68/ 99 (69%)	15.0441 (4.4210, 51.1933) /<.001	28.3720 (18.6659, 38.0780) /<.001	1.4131 (1.2319, 1.6209) /<.001	
NNRTI	148/155 (95%)	116/155 (75%)	7.1084 (3.0674, 16.4729) /<.001	20.6452 (13.0718, 28.2185) /<.001	1.2759 (1.1573, 1.4065) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
PI	30/ 51 (59%)	24/ 54 (44%)	1.7857 (0.8235, 3.8722) /0.142	14.3791 (-4.5442, 33.3024) /0.136	1.3235 (0.9084, 1.9283) /0.144	0.720
INI	63/102 (62%)	54/ 99 (55%)	1.3462 (0.7673, 2.3617) /0.300	7.2193 (-6.3876, 20.8261) /0.298	1.1324 (0.8944, 1.4336) /0.302	
NNRTI	96/155 (62%)	86/155 (55%)	1.3055 (0.8297, 2.0541) /0.249	6.4516 (-4.4865, 17.3897) /0.248	1.1163 (0.9255, 1.3463) /0.250	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
PI	7/ 51 (14%)	6/ 54 (11%)	1.2727 (0.3971, 4.0787) /0.685	2.6144 (-10.0131, 15.2419) /0.685	1.2353 (0.4450, 3.4293) /0.685	0.999
INI	18/102 (18%)	14/ 99 (14%)	1.3010 (0.6080, 2.7840) /0.498	3.5056 (-6.5862, 13.5975) /0.496	1.2479 (0.6571, 2.3698) /0.499	
NNRTI	27/155 (17%)	22/155 (14%)	1.2752 (0.6908, 2.3540) /0.437	3.2258 (-4.8881, 11.3397) /0.436	1.2273 (0.7318, 2.0582) /0.438	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
PI	2/ 51 (4%)	1/ 54 (2%)	2.1633 (0.1901, 24.6136) /0.534	2.0697 (-4.3575, 8.4970) /0.528	2.1176 (0.1980, 22.6477) /0.535	0.326
INI	17/102 (17%)	9/ 99 (9%)	2.0000 (0.8458, 4.7293) /0.114	7.5758 (-1.6099, 16.7614) /0.106	1.8333 (0.8581, 3.9169) /0.118	
NNRTI	13/155 (8%)	15/155 (10%)	0.8545 (0.3923, 1.8612) /0.692	-1.2903 (-7.6704, 5.0898) /0.692	0.8667 (0.4267, 1.7602) /0.692	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.832
INI	7/102 (7%)	7/ 99 (7%)	0.9684 (0.3269, 2.8693) /0.954	-0.2080 (-7.2485, 6.8325) /0.954	0.9706 (0.3533, 2.6662) /0.954	
NNRTI	9/155 (6%)	6/155 (4%)	1.5308 (0.5315, 4.4093) /0.430	1.9355 (-2.8371, 6.7080) /0.427	1.5000 (0.5470, 4.1131) /0.431	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
PI	7/ 51 (14%)	5/ 54 (9%)	1.5591 (0.4614, 5.2687) /0.475	4.4662 (-7.7388, 16.6713) /0.473	1.4824 (0.5024, 4.3736) /0.476	0.140
INI	1/102 (<1%)	4/ 99 (4%)	0.2351 (0.0258, 2.1417) /0.199	-3.0600 (-7.3844, 1.2644) /0.165	0.2426 (0.0276, 2.1332) /0.202	
NNRTI	3/155 (2%)	8/155 (5%)	0.3627 (0.0944, 1.3936) /0.140	-3.2258 (-7.3289, 0.8773) /0.123	0.3750 (0.1014, 1.3872) /0.142	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis PI	3/ 51 (6%)	1/ 54 (2%)	3.3125 (0.3332, 32.9279) /0.307	4.0305 (-3.3608, 11.4218) /0.285	3.1765 (0.3414, 29.5579) /0.310	0.262
INI	3/102 (3%)	6/ 99 (6%)	0.4697 (0.1142, 1.9326) /0.295	-3.1194 (-8.8503, 2.6114) /0.286	0.4853 (0.1248, 1.8871) /0.297	
NNRTI	7/155 (5%)	5/155 (3%)	1.4189 (0.4404, 4.5712) /0.558	1.2903 (-3.0020, 5.5826) /0.556	1.4000 (0.4541, 4.3159) /0.558	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
PI	2/ 51 (4%)	4/ 54 (7%)	0.5102 (0.0893, 2.9141) /0.449	-3.4858 (-12.2706, 5.2989) /0.437	0.5294 (0.1013, 2.7668) /0.451	0.804
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	7/155 (5%)	7/155 (5%)	1.0000 (0.3423, 2.9216) />0.999	<0.0001 (-4.6232, 4.6232) />0.999	1.0000 (0.3593, 2.7835) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis						
PI	2/ 51 (4%)	1/ 54 (2%)	2.1633 (0.1901, 24.6136) /0.534	2.0697 (-4.3575, 8.4970) /0.528	2.1176 (0.1980, 22.6477) /0.535	0.160
INI	4/102 (4%)	3/ 99 (3%)	1.3061 (0.2848, 5.9909) /0.731	0.8913 (-4.1676, 5.9501) /0.730	1.2941 (0.2972, 5.6351) /0.731	
NNRTI	2/155 (1%)	8/155 (5%)	0.2402 (0.0502, 1.1499) /0.074	-3.8710 (-7.7809, 0.0390) /0.052	0.2500 (0.0539, 1.1585) /0.076	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.079
INI	1/102 (<1%)	4/ 99 (4%)	0.2351 (0.0258, 2.1417) /0.199	-3.0600 (-7.3844, 1.2644) /0.165	0.2426 (0.0276, 2.1332) /0.202	
NNRTI	9/155 (6%)	4/155 (3%)	2.3271 (0.7012, 7.7227) /0.168	3.2258 (-1.2223, 7.6739) /0.155	2.2500 (0.7078, 7.1527) /0.169	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	5/ 99 (5%)	0.3760 (0.0712, 1.9851) /0.249	-3.0897 (-8.1737, 1.9943) /0.234	0.3882 (0.0771, 1.9546) /0.251	
NNRTI	3/155 (2%)	5/155 (3%)	0.5921 (0.1390, 2.5217) /0.478	-1.2903 (-4.8175, 2.2368) /0.473	0.6000 (0.1459, 2.4673) /0.479	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.553
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	5/155 (3%)	4/155 (3%)	1.2583 (0.3315, 4.7772) /0.736	0.6452 (-3.0922, 4.3825) /0.735	1.2500 (0.3421, 4.5674) /0.736	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis						
PI	0/ 51	0/ 54	NC	NC	NC	0.349
INI	1/102 (<1%)	6/ 99 (6%)	0.1535 (0.0181, 1.2987) /0.085	-5.0802 (-10.1544, -0.0060) /0.050	0.1618 (0.0198, 1.3195) /0.089	
NNRTI	3/155 (2%)	3/155 (2%)	1.0000 (0.1987, 5.0330) />0.999	<0.0001 (-3.0672, 3.0672) />0.999	1.0000 (0.2050, 4.8780) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.052
INI	2/102 (2%)	3/ 99 (3%)	0.6400 (0.1046, 3.9145) /0.629	-1.0695 (-5.3871, 3.2481) /0.627	0.6471 (0.1105, 3.7900) /0.629	
NNRTI	5/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	6/155 (4%)	4/155 (3%)	1.5201 (0.4204, 5.4961) /0.523	1.2903 (-2.6407, 5.2214) /0.520	1.5000 (0.4317, 5.2115) /0.523	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	5/102 (5%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	3/155 (2%)	0.6623 (0.1091, 4.0197) /0.654	-0.6452 (-3.4488, 2.1585) /0.652	0.6667 (0.1130, 3.9347) /0.654	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.288
INI	4/102 (4%)	4/ 99 (4%)	0.9694 (0.2356, 3.9878) /0.966	-0.1188 (-5.5257, 5.2880) /0.966	0.9706 (0.2496, 3.7742) /0.966	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.999
INI	2/102 (2%)	2/ 99 (2%)	0.9700 (0.1340, 7.0238) /0.976	-0.0594 (-3.9221, 3.8033) /0.976	0.9706 (0.1394, 6.7565) /0.976	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.085
INI	1/102 (<1%)	2/ 99 (2%)	0.4802 (0.0428, 5.3818) /0.552	-1.0398 (-4.4068, 2.3272) /0.545	0.4853 (0.0447, 5.2671) /0.552	
NNRTI	4/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis						
PI	0/ 51	3/ 54 (6%)	<0.0001 (<0.0001, -) />0.999	-7.7020 (-36.3576, 20.9537) /0.598	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	4/155 (3%)	2/155 (1%)	2.0265 (0.3657, 11.2291) /0.419	1.2903 (-1.7736, 4.3542) /0.409	2.0000 (0.3717, 10.7603) /0.419	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	3/102 (3%)	3/ 99 (3%)	0.9697 (0.1910, 4.9233) /0.970	-0.0891 (-4.7958, 4.6176) /0.970	0.9706 (0.2007, 4.6944) /0.970	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	3/155 (2%)	1.0000 (0.1987, 5.0330) />0.999	<0.0001 (-3.0672, 3.0672) />0.999	1.0000 (0.2050, 4.8780) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	3/102 (3%)	1/ 99 (1%)	2.9697 (0.3037, 29.0436) /0.350	1.9311 (-1.8940, 5.7561) /0.322	2.9118 (0.3081, 27.5217) /0.351	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
PI	1/ 51 (2%)	2/ 54 (4%)	0.5200 (0.0457, 5.9163) /0.598	-1.7429 (-8.0557, 4.5699) /0.588	0.5294 (0.0495, 5.6619) /0.599	0.585
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute sinusitis						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
PI	0/ 51	0/ 54	NC	NC	NC	0.927
INI	1/102 (<1%)	2/ 99 (2%)	0.4802 (0.0428, 5.3818) /0.552	-1.0398 (-4.4068, 2.3272) /0.545	0.4853 (0.0447, 5.2671) /0.552	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
PI	0/ 51	2/ 54 (4%)	<0.0001 (<0.0001, -) />0.999	-5.9276 (-34.4654, 22.6101) /0.684	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	2/155 (1%)	0.4968 (0.0446, 5.5356) /0.569	-0.6452 (-2.8235, 1.5332) /0.562	0.5000 (0.0458, 5.4573) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	3/155 (2%)	1/155 (<1%)	3.0395 (0.3127, 29.5452) /0.338	1.2903 (-1.2182, 3.7988) /0.313	3.0000 (0.3155, 28.5257) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
PI	0/ 51	0/ 54	NC	NC	NC	>0.999
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Onychomycosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	2/ 99 (2%)	0.4802 (0.0428, 5.3818) /0.552	-1.0398 (-4.4068, 2.3272) /0.545	0.4853 (0.0447, 5.2671) /0.552	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea versicolour						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.408
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acarodermatitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Candida infection						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	>0.999
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea cruris						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic tonsillitis						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impetigo						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site cellulitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pulpitis dental						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis chlamydial						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Acute hepatitis B						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis C						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Amoebiasis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal human papilloma virus infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Appendicitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervicitis human papilloma virus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Clostridium difficile colitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis bacterial						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis infectious						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Epididymitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Folliculitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastric infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal viral infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Groin abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes virus infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infected bite						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection parasitic						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Liver abscess PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Localised infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Nasal herpes						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral candidiasis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Periodontitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pertussis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia mycoplasmal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Primary syphilis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis chlamydial						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis herpes						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotavirus infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted disease						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin candida						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tinea pedis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue fungal infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ureaplasma infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral tonsillitis						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal candidiasis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginitis trichomonal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
PI	41/ 51 (80%)	4/ 54 (7%)	51.2500 (14.9670, 175.4901) /<.001	72.9847 (60.0416, 85.9279) /<.001	10.8529 (4.1860, 28.1378) /<.001	NC
INI	85/102 (83%)	8/ 99 (8%)	56.8750 (23.3369, 138.6114) /<.001	75.2525 (66.2453, 84.2597) /<.001	10.3125 (5.2769, 20.1533) /<.001	
NNRTI	126/155 (81%)	10/155 (6%)	63.0000 (29.5409, 134.3559) /<.001	74.8387 (67.5826, 82.0949) /<.001	12.6000 (6.8860, 23.0555) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain PI	40/ 51 (78%)	0/ 54	>999 (>999, >999) /NC	NC	NC	NC
INI	76/102 (75%)	0/ 99	>999 (>999, >999) /NC	NC	NC	
NNRTI	115/155 (74%)	0/155	>999 (>999, >999) /NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site module						
PI	11/ 51 (22%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	12/102 (12%)	0/ 99	>999 (>999, >999) /NC	13.6217 (-7.3088, 34.5523) /0.202	>999 (>999, >999) /NC	
NNRTI	14/155 (9%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
PI	7/ 51 (14%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	6/102 (6%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	17/155 (11%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.132
INI	5/102 (5%)	5/ 99 (5%)	0.9691 (0.2717, 3.4564) /0.961	-0.1485 (-6.1622, 5.8651) /0.961	0.9706 (0.2899, 3.2495) /0.961	
NNRTI	15/155 (10%)	3/155 (2%)	5.4286 (1.5388, 19.1509) /0.009	7.7419 (2.6070, 12.8768) /0.003	5.0000 (1.4770, 16.9263) /0.010	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue PI	3/ 51 (6%)	1/ 54 (2%)	3.3125 (0.3332, 32.9279) /0.307	4.0305 (-3.3608, 11.4218) /0.285	3.1765 (0.3414, 29.5579) /0.310	0.405
INI	10/102 (10%)	1/ 99 (1%)	10.6522 (1.3371, 84.8588) /0.025	8.7938 (2.6960, 14.8916) /0.005	9.7059 (1.2659, 74.4164) /0.029	
NNRTI	9/155 (6%)	4/155 (3%)	2.3271 (0.7012, 7.7227) /0.168	3.2258 (-1.2223, 7.6739) /0.155	2.2500 (0.7078, 7.1527) /0.169	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
PI	4/ 51 (8%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	8/102 (8%)	0/ 99	>999 (>999, >999) /NC	9.8854 (-10.8302, 30.6011) /0.350	>999 (>999, >999) /NC	
NNRTI	11/155 (7%)	0/155	>999 (>999, >999) /NC	9.1736 (-7.3722, 25.7194) /0.277	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.239
INI	2/102 (2%)	2/ 99 (2%)	0.9700 (0.1340, 7.0238) /0.976	-0.0594 (-3.9221, 3.8033) /0.976	0.9706 (0.1394, 6.7565) /0.976	
NNRTI	8/155 (5%)	1/155 (<1%)	8.3809 (1.0355, 67.8341) /0.046	4.5161 (0.8121, 8.2202) /0.017	8.0000 (1.0126, 63.2023) /0.049	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
PI	7/ 51 (14%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	5/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site bruising						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	4/102 (4%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	6/155 (4%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	4/102 (4%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	4/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	>0.999
INI	3/102 (3%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	4/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haematoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	3/102 (3%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	4/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	5/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site warmth						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	4/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site reaction						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cyst PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oedema peripheral						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling of body temperature change						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site anaesthesia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral swelling						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vessel puncture site pain						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
PI	9/ 51 (18%)	4/ 54 (7%)	2.6786 (0.7696, 9.3229) /0.122	10.2397 (-2.3404, 22.8197) /0.111	2.3824 (0.7821, 7.2570) /0.127	0.539
INI	25/102 (25%)	13/ 99 (13%)	2.1479 (1.0275, 4.4899) /0.042	11.3785 (0.7040, 22.0530) /0.037	1.8665 (1.0137, 3.4369) /0.045	
NNRTI	40/155 (26%)	29/155 (19%)	1.5112 (0.8800, 2.5952) /0.134	7.0968 (-2.1307, 16.3242) /0.132	1.3793 (0.9036, 2.1056) /0.136	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.270
INI	9/102 (9%)	8/ 99 (8%)	1.1008 (0.4069, 2.9781) /0.850	0.7427 (-6.9463, 8.4317) /0.850	1.0919 (0.4389, 2.7163) /0.850	
NNRTI	11/155 (7%)	7/155 (5%)	1.6151 (0.6092, 4.2819) /0.335	2.5806 (-2.6181, 7.7794) /0.331	1.5714 (0.6256, 3.9475) /0.336	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.495
INI	7/102 (7%)	3/ 99 (3%)	2.3579 (0.5921, 9.3905) /0.224	3.8324 (-2.1236, 9.7885) /0.207	2.2647 (0.6026, 8.5111) /0.226	
NNRTI	5/155 (3%)	2/155 (1%)	2.5500 (0.4872, 13.3472) /0.268	1.9355 (-1.3650, 5.2360) /0.250	2.5000 (0.4925, 12.6915) /0.269	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache						
PI	0/ 51	0/ 54	NC	NC	NC	0.694
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	3/155 (2%)	5/155 (3%)	0.5921 (0.1390, 2.5217) /0.478	-1.2903 (-4.8175, 2.2368) /0.473	0.6000 (0.1459, 2.4673) /0.479	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.042
INI	1/102 (<1%)	3/ 99 (3%)	0.3168 (0.0324, 3.0986) /0.323	-2.0499 (-5.9304, 1.8306) /0.300	0.3235 (0.0342, 3.0580) /0.325	
NNRTI	4/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.431
INI	3/102 (3%)	1/ 99 (1%)	2.9697 (0.3037, 29.0436) /0.350	1.9311 (-1.8940, 5.7561) /0.322	2.9118 (0.3081, 27.5217) /0.351	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.252
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	2/155 (1%)	1.5099 (0.2488, 9.1636) /0.654	0.6452 (-2.1585, 3.4488) /0.652	1.5000 (0.2542, 8.8530) /0.654	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.422
INI	3/102 (3%)	2/ 99 (2%)	1.4697 (0.2403, 8.9892) /0.677	0.9210 (-3.3722, 5.2142) /0.674	1.4559 (0.2486, 8.5276) /0.677	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	1/155 (<1%)	3.0395 (0.3127, 29.5452) /0.338	1.2903 (-1.2182, 3.7988) /0.313	3.0000 (0.3155, 28.5257) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.573
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	4/155 (3%)	0.2451 (0.0271, 2.2184) /0.211	-1.9355 (-4.7318, 0.8608) /0.175	0.2500 (0.0283, 2.2115) /0.213	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aphthous ulcer						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental caries						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Odynophagia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	
Abdominal distension						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal hernia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal pruritus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal skin tags						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Chronic gastritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphagia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Eosinophilic oesophagitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epigastric discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Functional gastrointestinal disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids thrombosed						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritable bowel syndrome						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip dry						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Lip swelling						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mouth ulceration						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral pain						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Pancreatitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis chronic						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis ulcerative						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Steatorrhoea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue ulceration						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
----- Tooth impacted						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Umbilical hernia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
PI	8/ 51 (16%)	5/ 54 (9%)	1.8233 (0.5546, 5.9934) /0.323	6.4270 (-6.1979, 19.0520) /0.318	1.6941 (0.5930, 4.8401) /0.325	0.833
INI	26/102 (25%)	18/ 99 (18%)	1.5395 (0.7818, 3.0314) /0.212	7.3084 (-4.0605, 18.6773) /0.208	1.4020 (0.8223, 2.3904) /0.215	
NNRTI	35/155 (23%)	20/155 (13%)	1.9687 (1.0784, 3.5942) /0.027	9.6774 (1.2407, 18.1142) /0.025	1.7500 (1.0590, 2.8918) /0.029	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain PI	4/ 51 (8%)	1/ 54 (2%)	4.5106 (0.4869, 41.7899) /0.185	5.9913 (-2.2168, 14.1994) /0.153	4.2353 (0.4896, 36.6378) /0.190	0.577
INI	9/102 (9%)	6/ 99 (6%)	1.5000 (0.5134, 4.3828) /0.459	2.7629 (-4.4752, 10.0010) /0.454	1.4559 (0.5381, 3.9389) /0.460	
NNRTI	8/155 (5%)	3/155 (2%)	2.7574 (0.7176, 10.5953) /0.140	3.2258 (-0.8773, 7.3289) /0.123	2.6667 (0.7209, 9.8643) /0.142	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	5/155 (3%)	7/155 (5%)	0.7048 (0.2188, 2.2705) /0.558	-1.2903 (-5.5826, 3.0020) /0.556	0.7143 (0.2317, 2.2020) /0.558	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.598
INI	2/102 (2%)	4/ 99 (4%)	0.4750 (0.0850, 2.6538) /0.396	-2.0796 (-6.8002, 2.6410) /0.388	0.4853 (0.0909, 2.5901) /0.397	
NNRTI	3/155 (2%)	4/155 (3%)	0.7451 (0.1640, 3.3855) /0.703	-0.6452 (-3.9519, 2.6616) /0.702	0.7500 (0.1707, 3.2957) /0.703	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.111
INI	1/102 (<1%)	5/ 99 (5%)	0.1861 (0.0214, 1.6227) /0.128	-4.0701 (-8.7885, 0.6483) /0.091	0.1941 (0.0231, 1.6321) /0.131	
NNRTI	4/155 (3%)	3/155 (2%)	1.3422 (0.2954, 6.0987) /0.703	0.6452 (-2.6616, 3.9519) /0.702	1.3333 (0.3034, 5.8590) /0.703	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.481
INI	4/102 (4%)	1/ 99 (1%)	4.0000 (0.4392, 36.4309) /0.219	2.9115 (-1.3394, 7.1623) /0.179	3.8824 (0.4416, 34.1318) /0.221	
NNRTI	4/155 (3%)	2/155 (1%)	2.0265 (0.3657, 11.2291) /0.419	1.2903 (-1.7736, 4.3542) /0.409	2.0000 (0.3717, 10.7603) /0.419	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	3/ 99 (3%)	<0.0001 (<0.0001, -) />0.999	-5.2786 (-25.5041, 14.9468) /0.609	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	3/155 (2%)	1/155 (<1%)	3.0395 (0.3127, 29.5452) /0.338	1.2903 (-1.2182, 3.7988) /0.313	3.0000 (0.3155, 28.5257) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteoarthritis						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint swelling						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal pain						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropathy PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bursitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot deformity						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc protrusion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Osteopenia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	
Arthritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Costochondritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Dupuytren's contracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Exostosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Flank pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint effusion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle tightness						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myositis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Osteonecrosi s						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Patellofemoral pain syndrome						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Polyarthriti s						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhabdomyolysis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Scoliosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal osteoarthritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovial cyst						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temporomandibular joint syndrome						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tenosynovitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
PI	17/ 51 (33%)	6/ 54 (11%)	4.0000 (1.4292, 11.1952) /0.008	22.2222 (6.8065, 37.6379) /0.005	3.0000 (1.2843, 7.0076) /0.011	0.395
INI	16/102 (16%)	9/ 99 (9%)	1.8605 (0.7806, 4.4340) /0.161	6.5954 (-2.4533, 15.6440) /0.153	1.7255 (0.8002, 3.7207) /0.164	
NNRTI	31/155 (20%)	20/155 (13%)	1.6875 (0.9144, 3.1142) /0.094	7.0968 (-1.1194, 15.3130) /0.090	1.5500 (0.9250, 2.5972) /0.096	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
PI	9/ 51 (18%)	6/ 54 (11%)	1.7143 (0.5633, 5.2169) /0.343	6.5359 (-6.8702, 19.9421) /0.339	1.5882 (0.6084, 4.1459) /0.345	0.840
INI	5/102 (5%)	2/ 99 (2%)	2.5000 (0.4735, 13.1983) /0.280	2.8818 (-2.1419, 7.9054) /0.261	2.4265 (0.4820, 12.2164) /0.282	
NNRTI	20/155 (13%)	9/155 (6%)	2.4033 (1.0577, 5.4609) /0.036	7.0968 (0.6619, 13.5316) /0.031	2.2222 (1.0449, 4.7259) /0.038	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.210
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	6/155 (4%)	5/155 (3%)	1.2081 (0.3609, 4.0442) /0.759	0.6452 (-3.4730, 4.7633) /0.759	1.2000 (0.3740, 3.8500) /0.759	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica PI	3/ 51 (6%)	0/ 54	>999 (>999, >999) /NC	8.0142 (-19.9986, 36.0271) /0.575	>999 (>999, >999) /NC	0.316
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.573
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	3/102 (3%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervicobrachial syndrome						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	2/155 (1%)	0.4968 (0.0446, 5.5356) /0.569	-0.6452 (-2.8235, 1.5332) /0.562	0.5000 (0.0458, 5.4573) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuralgia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syncope PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia ^a						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Presyncope						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Somnolence						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anterograde amnesia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Autonomic nervous system imbalance						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Burning sensation						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebral cyst						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebrovascular accident						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cognitive disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Dysaesthesia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysgeusia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Dystonia						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Essential tremor						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Facial paralysis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intercostal neuralgia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Loss of consciousness						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Memory impairment						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contractions involuntary						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuromuscular blockade						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post herpetic neuralgia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post-traumatic headache						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seizure PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Tension headache PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
(Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
--------------------	----------------	---------------------	---------------------	---------------------	---------------------	---------------------------

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
PI	3/ 51 (6%)	4/ 54 (7%)	0.7813 (0.1661, 3.6752) /0.755	-1.5251 (-11.0378, 7.9877) /0.753	0.7941 (0.1868, 3.3760) /0.755	0.860
INI	13/102 (13%)	14/ 99 (14%)	0.8868 (0.3940, 1.9962) /0.772	-1.3963 (-10.8300, 8.0374) /0.772	0.9013 (0.4465, 1.8194) /0.772	
NNRTI	20/155 (13%)	18/155 (12%)	1.1276 (0.5714, 2.2250) /0.729	1.2903 (-6.0098, 8.5904) /0.729	1.1111 (0.6119, 2.0177) /0.729	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough PI	0/ 51	2/ 54 (4%)	<0.0001 (<0.0001, -) />0.999	-5.9276 (-34.4654, 22.6101) /0.684	<0.0001 (<0.0001, -) />0.999	0.206
INI	6/102 (6%)	4/ 99 (4%)	1.4844 (0.4059, 5.4279) /0.550	1.8419 (-4.1493, 7.8332) /0.547	1.4559 (0.4236, 5.0037) /0.551	
NNRTI	10/155 (6%)	8/155 (5%)	1.2672 (0.4864, 3.3016) /0.628	1.2903 (-3.9144, 6.4950) /0.627	1.2500 (0.5069, 3.0826) /0.628	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.407
INI	3/102 (3%)	5/ 99 (5%)	0.5697 (0.1324, 2.4504) /0.450	-2.1093 (-7.5277, 3.3090) /0.445	0.5824 (0.1430, 2.3720) /0.451	
NNRTI	6/155 (4%)	5/155 (3%)	1.2081 (0.3609, 4.0442) /0.759	0.6452 (-3.4730, 4.7633) /0.759	1.2000 (0.3740, 3.8500) /0.759	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	4/155 (3%)	0.2451 (0.0271, 2.2184) /0.211	-1.9355 (-4.7318, 0.8608) /0.175	0.2500 (0.0283, 2.2115) /0.213	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus congestion						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.152
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory disorder						
PI	2/ 51 (4%)	1/ 54 (2%)	2.1633 (0.1901, 24.6136) /0.534	2.0697 (-4.3575, 8.4970) /0.528	2.1176 (0.1980, 22.6477) /0.535	0.217
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphonia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract congestion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspnoea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Productive cough						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract congestion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchospasm						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Emphysema						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lung disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal obstruction						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal septum deviation						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Pneumonitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pulmonary mass						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Reflux laryngitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory distress						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Sinus pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep apnoea syndrome						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wheezing						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
PI	7/ 51 (14%)	3/ 54 (6%)	2.7045 (0.6594, 11.0926) /0.167	8.1699 (-3.0782, 19.4180) /0.155	2.4706 (0.6752, 9.0402) /0.172	0.310
INI	12/102 (12%)	14/ 99 (14%)	0.8095 (0.3544, 1.8492) /0.616	-2.3767 (-11.6615, 6.9081) /0.616	0.8319 (0.4050, 1.7087) /0.616	
NNRTI	18/155 (12%)	14/155 (9%)	1.3232 (0.6333, 2.7650) /0.456	2.5806 (-4.1871, 9.3484) /0.455	1.2857 (0.6632, 2.4926) /0.457	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
PI	0/ 51	0/ 54	NC	NC	NC	>0.999
INI	3/102 (3%)	1/ 99 (1%)	2.9697 (0.3037, 29.0436) /0.350	1.9311 (-1.8940, 5.7561) /0.322	2.9118 (0.3081, 27.5217) /0.351	
NNRTI	3/155 (2%)	1/155 (<1%)	3.0395 (0.3127, 29.5452) /0.338	1.2903 (-1.2182, 3.7988) /0.313	3.0000 (0.3155, 28.5257) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.029
INI	0/102	3/ 99 (3%)	<0.0001 (<0.0001, -) />0.999	-5.2786 (-25.5041, 14.9468) /0.609	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	2/155 (1%)	0.4968 (0.0446, 5.5356) /0.569	-0.6452 (-2.8235, 1.5332) /0.562	0.5000 (0.0458, 5.4573) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.400
INI	1/102 (<1%)	2/ 99 (2%)	0.4802 (0.0428, 5.3818) /0.552	-1.0398 (-4.4068, 2.3272) /0.545	0.4853 (0.0447, 5.2671) /0.552	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.948
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Procedural pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	2/ 99 (2%)	0.4802 (0.0428, 5.3818) /0.552	-1.0398 (-4.4068, 2.3272) /0.545	0.4853 (0.0447, 5.2671) /0.552	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epicondylitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exposure to communicable disease						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Road traffic accident						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bone contusion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection related reaction						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Radius fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Soft tissue injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper limb fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Buttock injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Eye injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Facial bones fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Humerus fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injury corneal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint dislocation						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament rupture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Meniscus injury						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural complication						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Skin abrasion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skull fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Splinter						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon rupture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth fracture						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
PI	10/ 51 (20%)	4/ 54 (7%)	3.0488 (0.8904, 10.4396) /0.076	12.2004 (-0.7427, 25.1435) /0.065	2.6471 (0.8859, 7.9090) /0.081	0.331
INI	9/102 (9%)	4/ 99 (4%)	2.2984 (0.6840, 7.7230) /0.178	4.7831 (-1.9506, 11.5168) /0.164	2.1838 (0.6950, 6.8616) /0.181	
NNRTI	17/155 (11%)	15/155 (10%)	1.1498 (0.5524, 2.3931) /0.709	1.2903 (-5.4820, 8.0626) /0.709	1.1333 (0.5871, 2.1876) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.134
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	4/155 (3%)	0.7451 (0.1640, 3.3855) /0.703	-0.6452 (-3.9519, 2.6616) /0.702	0.7500 (0.1707, 3.2957) /0.703	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.595
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	2/155 (1%)	1.5099 (0.2488, 9.1636) /0.654	0.6452 (-2.1585, 3.4488) /0.652	1.5000 (0.2542, 8.8530) /0.654	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	4/155 (3%)	2/155 (1%)	2.0265 (0.3657, 11.2291) /0.419	1.2903 (-1.7736, 4.3542) /0.409	2.0000 (0.3717, 10.7603) /0.419	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood pressure increased						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	3/155 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2115 (-20.5981, 12.1752) /0.614	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
PI	4/ 51 (8%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine decreased						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood phosphorus decreased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Activated partial thromboplastin time prolonged						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin increased						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
ECG signs of ventricular hypertrophy						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glycosylated haemoglobin increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic enzyme increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipids increased						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neisseria test positive						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatic enzymes increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thyroxine free decreased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Weight increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
PI	5/ 51 (10%)	2/ 54 (4%)	2.8261 (0.5230, 15.2719) /0.227	6.1002 (-3.4903, 15.6907) /0.213	2.6471 (0.5374, 13.0396) /0.231	0.702
INI	12/102 (12%)	9/ 99 (9%)	1.3333 (0.5355, 3.3201) /0.537	2.6738 (-5.7620, 11.1096) /0.534	1.2941 (0.5706, 2.9349) /0.537	
NNRTI	19/155 (12%)	11/155 (7%)	1.8289 (0.8395, 3.9843) /0.129	5.1613 (-1.3958, 11.7184) /0.123	1.7273 (0.8506, 3.5077) /0.130	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
PI	2/ 51 (4%)	1/ 54 (2%)	2.1633 (0.1901, 24.6136) /0.534	2.0697 (-4.3575, 8.4970) /0.528	2.1176 (0.1980, 22.6477) /0.535	0.909
INI	5/102 (5%)	2/ 99 (2%)	2.5000 (0.4735, 13.1983) /0.280	2.8818 (-2.1419, 7.9054) /0.261	2.4265 (0.4820, 12.2164) /0.282	
NNRTI	4/155 (3%)	1/155 (<1%)	4.0795 (0.4508, 36.9195) /0.211	1.9355 (-0.8608, 4.7318) /0.175	4.0000 (0.4522, 35.3840) /0.213	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.334
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	3/102 (3%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acne PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash pruritic						
PI	0/ 51	0/ 54	NC	NC	NC	>0.999
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alopecia PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash generalised						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoeic dermatitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ecchymosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urticaria						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decubitus ulcer						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Dermatitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Dermatitis acneiform						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis contact						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Intertrigo						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nail bed bleeding						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neurodermatitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Onychoclasia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Photosensitivity reaction						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Purpura						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash erythematous						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash maculo-papular						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sebacous hyperplasia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin fissures						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin lesion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Skin mass						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stasis dermatitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
PI	6/ 51 (12%)	1/ 54 (2%)	7.0667 (0.8199, 60.9071) /0.075	9.9129 (0.3672, 19.4585) /0.042	6.3529 (0.7920, 50.9601) /0.082	0.134
INI	9/102 (9%)	10/ 99 (10%)	0.8613 (0.3343, 2.2188) /0.757	-1.2775 (-9.3728, 6.8178) /0.757	0.8735 (0.3707, 2.0582) /0.757	
NNRTI	17/155 (11%)	13/155 (8%)	1.3456 (0.6298, 2.8749) /0.443	2.5806 (-3.9953, 9.1566) /0.442	1.3077 (0.6579, 2.5992) /0.444	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia PI	2/ 51 (4%)	1/ 54 (2%)	2.1633 (0.1901, 24.6136) /0.534	2.0697 (-4.3575, 8.4970) /0.528	2.1176 (0.1980, 22.6477) /0.535	0.113
INI	6/102 (6%)	3/ 99 (3%)	2.0000 (0.4861, 8.2287) /0.337	2.8520 (-2.8271, 8.5312) /0.325	1.9412 (0.4992, 7.5483) /0.338	
NNRTI	7/155 (5%)	0/155	>999 (>999, >999) /NC	6.7073 (-9.7272, 23.1418) /0.424	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety PI	3/ 51 (6%)	0/ 54	>999 (>999, >999) /NC	8.0142 (-19.9986, 36.0271) /0.575	>999 (>999, >999) /NC	0.077
INI	2/102 (2%)	4/ 99 (4%)	0.4750 (0.0850, 2.6538) /0.396	-2.0796 (-6.8002, 2.6410) /0.388	0.4853 (0.0909, 2.5901) /0.397	
NNRTI	3/155 (2%)	3/155 (2%)	1.0000 (0.1987, 5.0330) />0.999	<0.0001 (-3.0672, 3.0672) />0.999	1.0000 (0.2050, 4.8780) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.026
INI	0/102	3/ 99 (3%)	<0.0001 (<0.0001, -) />0.999	-5.2786 (-25.5041, 14.9468) /0.609	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	3/155 (2%)	0.3290 (0.0338, 3.1981) /0.338	-1.2903 (-3.7988, 1.2182) /0.313	0.3333 (0.0351, 3.1695) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	2/155 (1%)	0.4968 (0.0446, 5.5356) /0.569	-0.6452 (-2.8235, 1.5332) /0.562	0.5000 (0.0458, 5.4573) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	2/155 (1%)	0.4968 (0.0446, 5.5356) /0.569	-0.6452 (-2.8235, 1.5332) /0.562	0.5000 (0.0458, 5.4573) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute stress disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Affect lability						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression suicidal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug dependence						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritability						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Mood altered						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mood swings						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Panic disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal behaviour						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thinking abnormal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
PI	0/ 51	4/ 54 (7%)	<0.0001 (<0.0001, -) />0.999	-9.4699 (-38.2621, 19.3223) /0.519	<0.0001 (<0.0001, -) />0.999	0.169
INI	5/102 (5%)	7/ 99 (7%)	0.6775 (0.2076, 2.2104) /0.519	-2.1687 (-8.7302, 4.3927) /0.517	0.6933 (0.2276, 2.1117) /0.519	
NNRTI	9/155 (6%)	16/155 (10%)	0.5355 (0.2291, 1.2517) /0.149	-4.5161 (-10.5574, 1.5252) /0.143	0.5625 (0.2564, 1.2341) /0.151	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
PI	0/ 51	2/ 54 (4%)	<0.0001 (<0.0001, -) />0.999	-5.9276 (-34.4654, 22.6101) /0.684	<0.0001 (<0.0001, -) />0.999	0.345
INI	3/102 (3%)	4/ 99 (4%)	0.7197 (0.1569, 3.3011) /0.672	-1.0992 (-6.1782, 3.9797) /0.671	0.7279 (0.1672, 3.1697) /0.672	
NNRTI	5/155 (3%)	6/155 (4%)	0.8278 (0.2473, 2.7712) /0.759	-0.6452 (-4.7633, 3.4730) /0.759	0.8333 (0.2597, 2.6736) /0.759	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	4/155 (3%)	<0.0001 (<0.0001, -) />0.999	-4.8429 (-21.2244, 11.5386) /0.562	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decreased appetite						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dehydration						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gout						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperglycaemia						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertriglyceridaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphat aemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Increased appetite						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetes mellitus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetic ketoacidosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Hypokalaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impaired fasting glucose						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B12 deficiency						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B6 deficiency						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
PI	5/ 51 (10%)	0/ 54	>999 (>999, >999) /NC	11.7542 (-16.5766, 40.0850) /0.416	>999 (>999, >999) /NC	0.068
INI	4/102 (4%)	4/ 99 (4%)	0.9694 (0.2356, 3.9878) /0.966	-0.1188 (-5.5257, 5.2880) /0.966	0.9706 (0.2496, 3.7742) /0.966	
NNRTI	7/155 (5%)	3/155 (2%)	2.3964 (0.6081, 9.4430) /0.212	2.5806 (-1.3425, 6.5038) /0.197	2.3333 (0.6146, 8.8583) /0.213	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign prostatic hyperplasia						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menorrhagia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Balanoposthitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysmenorrhoea ^a						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenomyosis						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Breast cyst						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Breast mass						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Breast pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysfunctional uterine bleeding						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital erythema						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Menometrorrhagia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menstrual disorder						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Metrorrhagia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ovarian cyst ruptured						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Penile pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scrotal mass						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal discharge						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal haemorrhage						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
PI	0/ 51	3/ 54 (6%)	<0.0001 (<0.0001, -) />0.999	-7.7020 (-36.3576, 20.9537) /0.598	<0.0001 (<0.0001, -) />0.999	0.161
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	8/155 (5%)	8/155 (5%)	1.0000 (0.3656, 2.7354) />0.999	<0.0001 (-4.9257, 4.9257) />0.999	1.0000 (0.3851, 2.5970) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	4/155 (3%)	5/155 (3%)	0.7947 (0.2093, 3.0170) /0.736	-0.6452 (-4.3825, 3.0922) /0.735	0.8000 (0.2189, 2.9231) /0.736	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia folate deficiency						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deficiency anaemia						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Eosinophilia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Leukocytosis						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Microcytic anaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Neutropenia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thrombocytopenia						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
PI	4/ 51 (8%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.050
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	9/155 (6%)	6/155 (4%)	1.5308 (0.5315, 4.4093) /0.430	1.9355 (-2.8371, 6.7080) /0.427	1.5000 (0.5470, 4.1131) /0.431	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	7/155 (5%)	3/155 (2%)	2.3964 (0.6081, 9.4430) /0.212	2.5806 (-1.3425, 6.5038) /0.197	2.3333 (0.6146, 8.8583) /0.213	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Deep vein thrombosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Hot flush						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertensive crisis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Orthostatic hypotension						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Phlebitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicophlebitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicose vein						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Venous thrombosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.264
INI	3/102 (3%)	2/ 99 (2%)	1.4697 (0.2403, 8.9892) /0.677	0.9210 (-3.3722, 5.2142) /0.674	1.4559 (0.2486, 8.5276) /0.677	
NNRTI	9/155 (6%)	3/155 (2%)	3.1233 (0.8292, 11.7649) /0.092	3.8710 (-0.4021, 8.1440) /0.076	3.0000 (0.8279, 10.8715) /0.094	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
PI	0/ 51	0/ 54	NC	NC	NC	>0.999
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal colic PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

19NOV2019 01:00

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal impairment						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic kidney disease						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Micturition urgency						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral discharge						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.365
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	5/155 (3%)	9/155 (6%)	0.5407 (0.1770, 1.6518) /0.281	-2.5806 (-7.1949, 2.0337) /0.273	0.5556 (0.1905, 1.6202) /0.282	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis allergic						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pruritus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid oedema						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vision blurred						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	
Blepharitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cataract subcapsular PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctival haemorrhage						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Dry eye						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Eye pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye swelling						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Lacrimation increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ocular hyperaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous haematoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.822
INI	4/102 (4%)	2/ 99 (2%)	1.9796 (0.3543, 11.0599) /0.437	1.9014 (-2.7752, 6.5780) /0.426	1.9412 (0.3637, 10.3605) /0.438	
NNRTI	4/155 (3%)	4/155 (3%)	1.0000 (0.2456, 4.0720) />0.999	<0.0001 (-3.5301, 3.5301) />0.999	1.0000 (0.2546, 3.9271) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.140
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Basal cell carcinoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fibrous histiocytoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Knuckle pads						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Melanocytic naevus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papillary thyroid cancer						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seminoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Skin papilloma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Squamous cell carcinoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Squamous cell carcinoma of skin						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	4/102 (4%)	2/ 99 (2%)	1.9796 (0.3543, 11.0599) /0.437	1.9014 (-2.7752, 6.5780) /0.426	1.9412 (0.3637, 10.3605) /0.438	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tinnitus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	
Vertigo						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Deafness						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Ear discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Excessive cerumen production						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.485
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Allergy to animal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug hypersensitivity						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycotic allergy						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiac disorders						
Any Event						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.338
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bradycardia						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Cardiovascular disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Palpitations						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Sinus tachycardia						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ventricular extrasystoles						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Endocrine disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	>0.999
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidism						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypogonadism						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Thyroid mass						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Biliary tract disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Hepatocellular injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbilirubinaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion missed						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion spontaneous						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Social circumstances						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menopause						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress at work						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	NC
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental implantation						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 OR = Odds Ratio, RD = Risk Difference in percentages, RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Overall						
Any Event						
<35	27/ 80 (34%)	36/ 80 (45%)	0.6226 (0.3285, 1.1801) /0.146	-11.2500 (-26.2903, 3.7903) /0.143	0.7500 (0.5072, 1.1089) /0.149	0.473
35 - <50	49/162 (30%)	45/132 (34%)	0.8383 (0.5126, 1.3710) /0.482	-3.8440 (-14.5873, 6.8993) /0.483	0.8872 (0.6359, 1.2379) /0.481	
>=50	25/ 66 (38%)	34/ 96 (35%)	1.1119 (0.5806, 2.1296) /0.749	2.4621 (-12.6536, 17.5779) /0.750	1.0695 (0.7095, 1.6122) /0.748	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	32/ 80 (40%)	30/ 80 (38%)	1.1111 (0.5880, 2.0995) /0.746	2.5000 (-12.5926, 17.5926) /0.745	1.0667 (0.7222, 1.5754) /0.746	0.850
35 - <50	64/162 (40%)	47/132 (36%)	1.1811 (0.7341, 1.9002) /0.493	3.9001 (-7.2083, 15.0085) /0.491	1.1095 (0.8234, 1.4951) /0.495	
>=50	29/ 66 (44%)	34/ 96 (35%)	1.4293 (0.7527, 2.7140) /0.275	8.5227 (-6.8037, 23.8492) /0.276	1.2406 (0.8453, 1.8209) /0.271	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis <35	10/ 80 (13%)	10/ 80 (13%)	1.0000 (0.3918, 2.5524) />0.999	<0.0001 (-10.2489, 10.2489) />0.999	1.0000 (0.4405, 2.2703) />0.999	0.987
35 - <50	20/162 (12%)	15/132 (11%)	1.0986 (0.5386, 2.2407) /0.796	0.9820 (-6.4323, 8.3964) /0.795	1.0864 (0.5793, 2.0374) /0.796	
>=50	10/ 66 (15%)	14/ 96 (15%)	1.0459 (0.4339, 2.5210) /0.920	0.5682 (-10.5974, 11.7338) /0.921	1.0390 (0.4915, 2.1963) /0.920	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Upper respiratory tract infection						
<35	7/ 80 (9%)	5/ 80 (6%)	1.4384 (0.4367, 4.7376) /0.550	2.5000 (-5.6532, 10.6532) /0.548	1.4000 (0.4637, 4.2269) /0.551	0.854
35 - <50	13/162 (8%)	10/132 (8%)	1.0644 (0.4511, 2.5115) /0.887	0.4489 (-5.7056, 6.6035) /0.886	1.0593 (0.4799, 2.3380) /0.887	
>=50	5/ 66 (8%)	8/ 96 (8%)	0.9016 (0.2815, 2.8880) /0.862	-0.7576 (-9.2027, 7.6876) /0.860	0.9091 (0.3110, 2.6570) /0.862	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Influenza <35	3/ 80 (4%)	2/ 80 (3%)	1.5195 (0.2470, 9.3470) /0.652	1.2500 (-4.1385, 6.6385) /0.649	1.5000 (0.2575, 8.7374) /0.652	0.558
35 - <50	8/162 (5%)	5/132 (4%)	1.3195 (0.4212, 4.1331) /0.634	1.1504 (-3.5120, 5.8128) /0.629	1.3037 (0.4368, 3.8910) /0.635	
>=50	5/ 66 (8%)	2/ 96 (2%)	3.8525 (0.7244, 20.4892) /0.114	5.4924 (-1.5016, 12.4864) /0.124	3.6364 (0.7272, 18.1847) /0.116	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
<35	0/ 80	4/ 80 (5%)	<0.0001 (<0.0001, -) />0.999	-7.1707 (-30.0734, 15.7321) /0.539	<0.0001 (<0.0001, -) />0.999	0.015
35 - <50	10/162 (6%)	5/132 (4%)	1.6710 (0.5568, 5.0154) /0.360	2.3850 (-2.5486, 7.3185) /0.343	1.6296 (0.5711, 4.6505) /0.361	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
<35	2/ 80 (3%)	5/ 80 (6%)	0.3846 (0.0724, 2.0435) /0.262	-3.7500 (-10.0619, 2.5619) /0.244	0.4000 (0.0799, 2.0017) /0.265	0.064
35 - <50	2/162 (1%)	7/132 (5%)	0.2232 (0.0456, 1.0933) /0.064	-4.0685 (-8.2525, 0.1155) /0.057	0.2328 (0.0492, 1.1019) /0.066	
>=50	3/ 66 (5%)	1/ 96 (1%)	4.5238 (0.4602, 44.4703) /0.196	3.5038 (-1.9164, 8.9240) /0.205	4.3636 (0.4639, 41.0452) /0.198	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Bronchitis <35	0/ 80	3/ 80 (4%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.048
35 - <50	6/162 (4%)	2/132 (2%)	2.5000 (0.4962, 12.5966) /0.267	2.1886 (-1.3891, 5.7662) /0.231	2.4444 (0.5016, 11.9119) /0.269	
>=50	3/ 66 (5%)	2/ 96 (2%)	2.2381 (0.3636, 13.7778) /0.385	2.4621 (-3.3186, 8.2428) /0.404	2.1818 (0.3748, 12.7011) /0.385	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
<35	6/ 80 (8%)	1/ 80 (1%)	6.4054 (0.7532, 54.4759) /0.089	6.2500 (-0.0142, 12.5142) /0.051	6.0000 (0.7390, 48.7136) /0.094	0.182
35 - <50	3/162 (2%)	2/132 (2%)	1.2264 (0.2019, 7.4501) /0.825	0.3367 (-2.6048, 3.2782) /0.822	1.2222 (0.2073, 7.2069) /0.825	
>=50	1/ 66 (2%)	3/ 96 (3%)	0.4769 (0.0485, 4.6873) /0.525	-1.6098 (-6.1705, 2.9508) /0.489	0.4848 (0.0515, 4.5606) /0.527	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis <35	3/ 80 (4%)	4/ 80 (5%)	0.7403 (0.1603, 3.4191) /0.700	-1.2500 (-7.5856, 5.0856) /0.699	0.7500 (0.1734, 3.2441) /0.700	0.628
35 - <50	2/162 (1%)	4/132 (3%)	0.4000 (0.0721, 2.2187) /0.295	-1.7957 (-5.1785, 1.5870) /0.298	0.4074 (0.0758, 2.1898) /0.295	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Pharyngitis <35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.505
35 - <50	2/162 (1%)	5/132 (4%)	0.3175 (0.0606, 1.6636) /0.175	-2.5533 (-6.2272, 1.1206) /0.173	0.3259 (0.0643, 1.6529) /0.176	
>=50	2/ 66 (3%)	2/ 96 (2%)	1.4687 (0.2017, 10.6968) /0.704	0.9470 (-4.0796, 5.9735) /0.712	1.4545 (0.2101, 10.0688) /0.704	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Lower respiratory tract infection						
<35	0/ 80	0/ 80	NC	NC	NC	0.338
35 - <50	5/162 (3%)	1/132 (<1%)	4.1720 (0.4814, 36.1585) /0.195	2.3288 (-0.7176, 5.3753) /0.134	4.0741 (0.4819, 34.4442) /0.197	
>=50	1/ 66 (2%)	3/ 96 (3%)	0.4769 (0.0485, 4.6873) /0.525	-1.6098 (-6.1705, 2.9508) /0.489	0.4848 (0.0515, 4.5606) /0.527	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Conjunctivitis <35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.093
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	3/ 66 (5%)	0/ 96	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Gonorrhoea <35	2/ 80 (3%)	1/ 80 (1%)	2.0256 (0.1800, 22.7973) /0.568	1.2500 (-2.9490, 5.4490) /0.560	2.0000 (0.1850, 21.6178) /0.568	0.246
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	2/ 96 (2%)	0.7231 (0.0642, 8.1413) /0.793	-0.5682 (-4.6728, 3.5364) /0.786	0.7273 (0.0673, 7.8574) /0.793	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Oral herpes <35	0/ 80	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.138
35 - <50	4/162 (2%)	2/132 (2%)	1.6456 (0.2967, 9.1272) /0.569	0.9540 (-2.2167, 4.1246) /0.555	1.6296 (0.3032, 8.7592) /0.569	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Sinusitis <35	2/ 80 (3%)	1/ 80 (1%)	2.0256 (0.1800, 22.7973) /0.568	1.2500 (-2.9490, 5.4490) /0.560	2.0000 (0.1850, 21.6178) /0.568	0.323
35 - <50	4/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Syphilis <35	2/ 80 (3%)	2/ 80 (3%)	1.0000 (0.1374, 7.2786) />0.999	<0.0001 (-4.8383, 4.8383) />0.999	1.0000 (0.1444, 6.9262) />0.999	NC
35 - <50	0/162	4/132 (3%)	<0.0001 (<0.0001, -) />0.999	-5.2786 (-21.4486, 10.8913) /0.522	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Viral upper respiratory tract infection						
<35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.176
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	0.446
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Gastroenteritis viral						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	4/162 (2%)	1/132 (<1%)	3.3165 (0.3662, 30.0363) /0.286	1.7116 (-1.0989, 4.5220) /0.233	3.2593 (0.3687, 28.8100) /0.288	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tonsillitis						
<35	2/ 80 (3%)	1/ 80 (1%)	2.0256 (0.1800, 22.7973) /0.568	1.2500 (-2.9490, 5.4490) /0.560	2.0000 (0.1850, 21.6178) /0.568	0.475
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Rhinitis <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.293
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Furuncle <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Acute sinusitis <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Hordeolum <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tinea cruris <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea versicolour						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Candida infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Cellulitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic tonsillitis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Fungal infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Genital herpes <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Genital herpes simplex						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Herpes zoster <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impetigo <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Onychomycosis <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Paronychia <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Proctitis gonococcal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Pulpitis dental <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tooth infection <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tracheitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Urethritis chlamydial						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Abscess <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
<hr/>						
Acarodermatitis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amoebiasis <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Anal chlamydia infection <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Anal infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Angular cheilitis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Anorectal human papilloma virus infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Body tinea						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Clostridium difficile colitis						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	NC
>=50	0/ 66	0/ 96	NC	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis bacterial						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Cystitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Ear infection						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Enteritis infectious						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Epididymitis <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Gastric infection <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Gastrointestina l infection						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Gastrointestina l viral infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival abscess						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Herpes virus infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Infection parasitic <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site cellulitis						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Laryngitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Nasal herpes						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Oropharyngeal gonococcal infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis media acute						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Pneumonia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Pneumonia mycoplasmal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post procedural infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Primary syphilis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted disease						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin candida <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	
<hr/>						
Staphylococcal infection <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Staphylococcal skin infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Subcutaneous abscess						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea pedis <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Tongue fungal infection <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tooth abscess <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Ureaplasma infection <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Urethritis gonococcal						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Vaginal infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Viral infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral tonsillitis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Vulvovaginal candidiasis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Vulvovaginitis trichomonal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	31/ 80 (39%)	7/ 80 (9%)	6.5976 (2.6918, 16.1709) /<.001	30.0000 (17.6587, 42.3413) /<.001	4.4286 (2.0724, 9.4637) /<.001	0.150
35 - <50	72/162 (44%)	4/132 (3%)	25.6000 (9.0276, 72.5955) /<.001	41.4141 (33.2226, 49.6057) /<.001	14.6666 (5.5031, 39.0885) /<.001	
>=50	32/ 66 (48%)	6/ 96 (6%)	14.1176 (5.4215, 36.7626) /<.001	42.2348 (29.2417, 55.2280) /<.001	7.7576 (3.4384, 17.5025) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injection site pain						
<35	31/ 80 (39%)	0/ 80	>999 (>999, >999) /NC	39.2978 (14.8992, 63.6964) /0.002	>999 (>999, >999) /NC	NC
35 - <50	70/162 (43%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	29/ 66 (44%)	0/ 96	>999 (>999, >999) /NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site nodule						
<35	6/ 80 (8%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35 - <50	19/162 (12%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	8/ 66 (12%)	0/ 96	>999 (>999, >999) /NC	13.9612 (-7.9190, 35.8414) /0.211	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Fatigue <35	4/ 80 (5%)	3/ 80 (4%)	1.3509 (0.2925, 6.2393) /0.700	1.2500 (-5.0856, 7.5856) /0.699	1.3333 (0.3083, 5.7673) /0.700	0.217
35 - <50	11/162 (7%)	1/132 (<1%)	9.5430 (1.2158, 74.9080) /0.032	6.0325 (1.8858, 10.1793) /0.004	8.9630 (1.1723, 68.5303) /0.035	
>=50	5/ 66 (8%)	1/ 96 (1%)	7.7869 (0.8882, 68.2667) /0.064	6.5341 (-0.1650, 13.2332) /0.056	7.2727 (0.8694, 60.8352) /0.067	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Pyrexia <35	5/ 80 (6%)	6/ 80 (8%)	0.8222 (0.2405, 2.8116) /0.755	-1.2500 (-9.0889, 6.5889) /0.755	0.8333 (0.2650, 2.6204) /0.755	0.085
35 - <50	9/162 (6%)	1/132 (<1%)	7.7059 (0.9635, 61.6269) /0.054	4.7980 (0.9731, 8.6229) /0.014	7.3333 (0.9411, 57.1450) /0.057	
>=50	3/ 66 (5%)	1/ 96 (1%)	4.5238 (0.4602, 44.4703) /0.196	3.5038 (-1.9164, 8.9240) /0.205	4.3636 (0.4639, 41.0452) /0.198	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
35 - <50	12/162 (7%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	5/ 66 (8%)	0/ 96	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
<35	5/ 80 (6%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35 - <50	8/162 (5%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	3/ 66 (5%)	0/ 96	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injection site erythema						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	8/162 (5%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	4/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	3/ 96 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-30.1817, 19.4415) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pruritus						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	5/162 (3%)	0/132	>999 (>999, >999) /NC	5.3329 (-12.2992, 22.9649) /0.553	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Asthenia <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	5/162 (3%)	0/132	>999 (>999, >999) /NC	5.3329 (-12.2992, 22.9649) /0.553	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	3/ 66 (5%)	0/ 96	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	4/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Chills						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Malaise <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.200
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Chest pain <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	>0.999
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Cyst <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Feeling hot <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Discomfort						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Feeling of body temperature change						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site anaesthesia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Injection site discolouration						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site discomfort						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-cardiac chest pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Oedema peripheral						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Gastrointestina l disorders						
Any Event						
<35	11/ 80 (14%)	8/ 80 (10%)	1.4348 (0.5446, 3.7801) /0.465	3.7500 (-6.2581, 13.7581) /0.463	1.3750 (0.5840, 3.2376) /0.466	0.742
35 - <50	27/162 (17%)	11/132 (8%)	2.2000 (1.0468, 4.6238) /0.037	8.3333 (0.9060, 15.7606) /0.028	2.0000 (1.0313, 3.8786) /0.040	
>=50	10/ 66 (15%)	10/ 96 (10%)	1.5357 (0.6005, 3.9271) /0.371	4.7348 (-5.8560, 15.3257) /0.381	1.4545 (0.6415, 3.2979) /0.370	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Diarrhoea <35	4/ 80 (5%)	4/ 80 (5%)	1.0000 (0.2413, 4.1450) />0.999	<0.0001 (-6.7541, 6.7541) />0.999	1.0000 (0.2590, 3.8606) />0.999	0.572
35 - <50	8/162 (5%)	4/132 (3%)	1.6623 (0.4893, 5.6470) /0.415	1.9080 (-2.5286, 6.3445) /0.399	1.6296 (0.5017, 5.2929) /0.417	
>=50	2/ 66 (3%)	5/ 96 (5%)	0.5688 (0.1070, 3.0234) /0.508	-2.1780 (-8.2492, 3.8931) /0.482	0.5818 (0.1163, 2.9096) /0.510	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	0.416
35 - <50	5/162 (3%)	1/132 (<1%)	4.1720 (0.4814, 36.1585) /0.195	2.3288 (-0.7176, 5.3753) /0.134	4.0741 (0.4819, 34.4442) /0.197	
>=50	3/ 66 (5%)	0/ 96	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Constipation <35	0/ 80	0/ 80	NC	NC	NC	0.997
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	2/ 66 (3%)	2/ 96 (2%)	1.4687 (0.2017, 10.6968) /0.704	0.9470 (-4.0796, 5.9735) /0.712	1.4545 (0.2101, 10.0688) /0.704	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.461
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	1/ 66 (2%)	2/ 96 (2%)	0.7231 (0.0642, 8.1413) /0.793	-0.5682 (-4.6728, 3.5364) /0.786	0.7273 (0.0673, 7.8574) /0.793	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Dyspepsia <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.161
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	1/ 96 (1%)	2.9687 (0.2636, 33.4293) /0.378	1.9886 (-2.6187, 6.5960) /0.398	2.9091 (0.2693, 31.4296) /0.379	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.327
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	2/ 96 (2%)	0.7231 (0.0642, 8.1413) /0.793	-0.5682 (-4.6728, 3.5364) /0.786	0.7273 (0.0673, 7.8574) /0.793	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Abdominal pain <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Flatulence						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Abdominal discomfort						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Abdominal pain upper						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Aphthous ulcer <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Gastritis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Abdominal distension						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Anal fissure						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal pruritus						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Anal skin tags						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal discomfort <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic gastritis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Dysphagia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Epigastric discomfort						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Gingival disorder <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoids thrombosed						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Lip dry <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip swelling <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Mouth ulceration <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Odynophagia <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Oral disorder <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Oral pain <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Proctitis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Steatorrhoea <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Tongue ulceration <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tooth impacted						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Umbilical hernia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	8/ 80 (10%)	6/ 80 (8%)	1.3704 (0.4529, 4.1462) /0.577	2.5000 (-6.2481, 11.2481) /0.575	1.3333 (0.4846, 3.6686) /0.577	0.747
35 - <50	28/162 (17%)	11/132 (8%)	2.2985 (1.0972, 4.8150) /0.027	8.9506 (1.4585, 16.4427) /0.019	2.0741 (1.0736, 4.0068) /0.030	
>=50	11/ 66 (17%)	10/ 96 (10%)	1.7200 (0.6849, 4.3195) /0.248	6.2500 (-4.6210, 17.1210) /0.260	1.6000 (0.7211, 3.5501) /0.248	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Back pain <35	3/ 80 (4%)	3/ 80 (4%)	1.0000 (0.1957, 5.1099) />0.999	<0.0001 (-5.8875, 5.8875) />0.999	1.0000 (0.2080, 4.8067) />0.999	0.858
35 - <50	6/162 (4%)	3/132 (2%)	1.6538 (0.4056, 6.7430) /0.483	1.4310 (-2.4318, 5.2937) /0.468	1.6296 (0.4155, 6.3921) /0.484	
>=50	2/ 66 (3%)	3/ 96 (3%)	0.9688 (0.1574, 5.9628) /0.973	-0.0947 (-5.5000, 5.3106) /0.973	0.9697 (0.1666, 5.6449) /0.973	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia <35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.709
35 - <50	2/162 (1%)	3/132 (2%)	0.5375 (0.0885, 3.2652) /0.500	-1.0382 (-4.0968, 2.0205) /0.506	0.5432 (0.0921, 3.2031) /0.500	
>=50	2/ 66 (3%)	2/ 96 (2%)	1.4687 (0.2017, 10.6968) /0.704	0.9470 (-4.0796, 5.9735) /0.712	1.4545 (0.2101, 10.0688) /0.704	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Myalgia <35	3/ 80 (4%)	1/ 80 (1%)	3.0779 (0.3133, 30.2376) /0.335	2.5000 (-2.3227, 7.3227) /0.310	3.0000 (0.3188, 28.2323) /0.337	0.478
35 - <50	3/162 (2%)	1/132 (<1%)	2.4717 (0.2541, 24.0434) /0.436	1.0943 (-1.4548, 3.6434) /0.400	2.4444 (0.2573, 23.2264) /0.437	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity <35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.650
35 - <50	1/162 (<1%)	3/132 (2%)	0.2671 (0.0275, 2.5981) /0.255	-1.6554 (-4.4694, 1.1585) /0.249	0.2716 (0.0286, 2.5807) /0.257	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.227
35 - <50	3/162 (2%)	2/132 (2%)	1.2264 (0.2019, 7.4501) /0.825	0.3367 (-2.6048, 3.2782) /0.822	1.2222 (0.2073, 7.2069) /0.825	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	2/ 66 (3%)	2/ 96 (2%)	1.4687 (0.2017, 10.6968) /0.704	0.9470 (-4.0796, 5.9735) /0.712	1.4545 (0.2101, 10.0688) /0.704	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Joint swelling						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Muscle contracture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Neck pain <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	>0.999
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal pain <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
<hr/>						
Bursitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Foot deformity						
<35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc protrusion						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Musculoskeletal chest pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Osteoarthritis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteopenia <35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	
Arthritis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Costochondritis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	
<hr/>						
Dupuytren's contracture <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Exostosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Flank pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Muscle tightness						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Patellofemoral pain syndrome						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Scoliosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovial cyst <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temporomandibular joint syndrome						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Tenosynovitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Nervous system disorders						
Any Event						
<35	9/ 80 (11%)	8/ 80 (10%)	1.1408 (0.4167, 3.1236) /0.798	1.2500 (-8.2978, 10.7978) /0.797	1.1250 (0.4571, 2.7686) /0.798	0.167
35 - <50	31/162 (19%)	8/132 (6%)	3.6679 (1.6234, 8.2874) /0.002	13.0752 (5.7771, 20.3733) /<.001	3.1574 (1.5027, 6.6342) /0.002	
>=50	8/ 66 (12%)	8/ 96 (8%)	1.5172 (0.5392, 4.2692) /0.430	3.7879 (-5.8332, 13.4090) /0.440	1.4545 (0.5747, 3.6811) /0.429	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache <35	4/ 80 (5%)	7/ 80 (9%)	0.5489 (0.1542, 1.9540) /0.354	-3.7500 (-11.5697, 4.0697) /0.347	0.5714 (0.1741, 1.8760) /0.356	0.011
35 - <50	22/162 (14%)	4/132 (3%)	5.0286 (1.6873, 14.9860) /0.004	10.5499 (4.5183, 16.5816) /<.001	4.4815 (1.5836, 12.6824) /0.005	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Dizziness <35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.194
35 - <50	2/162 (1%)	2/132 (2%)	0.8125 (0.1129, 5.8471) /0.837	-0.2806 (-2.9702, 2.4090) /0.838	0.8148 (0.1163, 5.7067) /0.837	
>=50	4/ 66 (6%)	2/ 96 (2%)	3.0323 (0.5390, 17.0595) /0.208	3.9773 (-2.4492, 10.4038) /0.225	2.9091 (0.5486, 15.4257) /0.210	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Paraesthesia <35	3/ 80 (4%)	1/ 80 (1%)	3.0779 (0.3133, 30.2376) /0.335	2.5000 (-2.3227, 7.3227) /0.310	3.0000 (0.3188, 28.2323) /0.337	0.279
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Sciatica <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.566
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	1/ 96 (1%)	2.9687 (0.2636, 33.4293) /0.378	1.9886 (-2.6187, 6.5960) /0.398	2.9091 (0.2693, 31.4296) /0.379	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Migraine						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Neuralgia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Cervicobrachial syndrome						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Hypoaesthesia <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Presyncope <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Somnolence <35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Anterograde amnesia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Autonomic nervous system imbalance						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Cerebral cyst <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Cognitive disorder <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Disturbance in attention						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Dysaesthesia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Dystonia <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Essential tremor <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Facial paralysis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Loss of consciousness						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Memory impairment						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post herpetic neuralgia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension headache						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	9/ 80 (11%)	12/ 80 (15%)	0.7183 (0.2845, 1.8134) /0.484	-3.7500 (-14.1983, 6.6983) /0.482	0.7500 (0.3347, 1.6805) /0.485	0.162
35 - <50	12/162 (7%)	7/132 (5%)	1.4286 (0.5460, 3.7381) /0.467	2.1044 (-3.4524, 7.6612) /0.458	1.3968 (0.5660, 3.4473) /0.468	
>=50	9/ 66 (14%)	5/ 96 (5%)	2.8737 (0.9170, 9.0056) /0.070	8.4280 (-0.9689, 17.8249) /0.079	2.6182 (0.9186, 7.4619) /0.072	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Cough <35	4/ 80 (5%)	3/ 80 (4%)	1.3509 (0.2925, 6.2393) /0.700	1.2500 (-5.0856, 7.5856) /0.699	1.3333 (0.3083, 5.7673) /0.700	0.983
35 - <50	6/162 (4%)	4/132 (3%)	1.2308 (0.3400, 4.4558) /0.752	0.6734 (-3.4508, 4.7976) /0.749	1.2222 (0.3522, 4.2409) /0.752	
>=50	4/ 66 (6%)	4/ 96 (4%)	1.4839 (0.3577, 6.1563) /0.587	1.8939 (-5.1143, 8.9022) /0.596	1.4545 (0.3771, 5.6108) /0.586	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
<35	4/ 80 (5%)	6/ 80 (8%)	0.6491 (0.1760, 2.3938) /0.516	-2.5000 (-9.9914, 4.9914) /0.513	0.6667 (0.1955, 2.2731) /0.517	0.293
35 - <50	2/162 (1%)	2/132 (2%)	0.8125 (0.1129, 5.8471) /0.837	-0.2806 (-2.9702, 2.4090) /0.838	0.8148 (0.1163, 5.7067) /0.837	
>=50	3/ 66 (5%)	1/ 96 (1%)	4.5238 (0.4602, 44.4703) /0.196	3.5038 (-1.9164, 8.9240) /0.205	4.3636 (0.4639, 41.0452) /0.198	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Nasal congestion						
<35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.472
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Sinus congestion						
<35	0/ 80	0/ 80	NC	NC	NC	0.998
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory disorder						
<35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Rhinorrhoea <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.267
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphonia <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspnoea <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Rhinitis allergic						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Emphysema <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	
Nasal obstruction <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Productive cough						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Pulmonary mass						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Reflux laryngitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract congestion						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus pain <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Sleep apnoea syndrome <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<35	8/ 80 (10%)	2/ 80 (3%)	4.3333 (0.8906, 21.0855) /0.069	7.5000 (0.0891, 14.9109) /0.047	4.0000 (0.8764, 18.2557) /0.074	0.093
35 - <50	13/162 (8%)	12/132 (9%)	0.8725 (0.3840, 1.9822) /0.745	-1.0662 (-7.5124, 5.3799) /0.746	0.8827 (0.4169, 1.8691) /0.744	
>=50	10/ 66 (15%)	6/ 96 (6%)	2.6786 (0.9228, 7.7754) /0.070	8.9015 (-1.0117, 18.8148) /0.078	2.4242 (0.9260, 6.3465) /0.071	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Rash						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.048
35 - <50	2/162 (1%)	3/132 (2%)	0.5375 (0.0885, 3.2652) /0.500	-1.0382 (-4.0968, 2.0205) /0.506	0.5432 (0.0921, 3.2031) /0.500	
>=50	5/ 66 (8%)	1/ 96 (1%)	7.7869 (0.8882, 68.2667) /0.064	6.5341 (-0.1650, 13.2332) /0.056	7.2727 (0.8694, 60.8352) /0.067	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.205
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	3/ 66 (5%)	1/ 96 (1%)	4.5238 (0.4602, 44.4703) /0.196	3.5038 (-1.9164, 8.9240) /0.205	4.3636 (0.4639, 41.0452) /0.198	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Acne <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Eczema						
<35	3/ 80 (4%)	1/ 80 (1%)	3.0779 (0.3133, 30.2376) /0.335	2.5000 (-2.3227, 7.3227) /0.310	3.0000 (0.3188, 28.2323) /0.337	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Rash pruritic <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Alopecia <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash generalised						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Seborrhoeic dermatitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Ecchymosis <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Dermatitis acneiform						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Dermatitis contact						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Nail bed bleeding						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Neurodermatitis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychoclasia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Photosensitivity reaction						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Pruritus generalised						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Purpura						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sebacous hyperplasia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Seborrhoea						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Skin fissures						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin lesion						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Skin mass						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Stasis dermatitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urticaria						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	4/ 80 (5%)	4/ 80 (5%)	1.0000 (0.2413, 4.1450) />0.999	<0.0001 (-6.7541, 6.7541) />0.999	1.0000 (0.2590, 3.8606) />0.999	0.001
35 - <50	14/162 (9%)	3/132 (2%)	4.0676 (1.1433, 14.4710) /0.030	6.3692 (1.3508, 11.3877) /0.013	3.8025 (1.1163, 12.9518) /0.033	
>=50	1/ 66 (2%)	12/ 96 (13%)	0.1077 (0.0137, 0.8496) /0.034	-10.9848 (-18.2272, -3.7425) /0.003	0.1212 (0.0161, 0.9099) /0.040	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Ligament sprain <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	0.357
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	0.139
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	3/ 96 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-30.1817, 19.4415) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	2/132 (2%)	0.8125 (0.1129, 5.8471) /0.837	-0.2806 (-2.9702, 2.4090) /0.838	0.8148 (0.1163, 5.7067) /0.837	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bone contusion <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Epicondylitis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exposure to communicable disease						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Procedural pain <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Soft tissue injury						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn <35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	
Animal bite <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Buttock injury <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Injection related reaction <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural complication						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Radius fracture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Rib fracture						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Road traffic accident						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Skin abrasion						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Splinter <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
<35	8/ 80 (10%)	5/ 80 (6%)	1.6667 (0.5208, 5.3336) /0.389	3.7500 (-4.6970, 12.1970) /0.384	1.6000 (0.5469, 4.6810) /0.391	0.890
35 - <50	10/162 (6%)	6/132 (5%)	1.3816 (0.4887, 3.9061) /0.542	1.6274 (-3.5069, 6.7617) /0.534	1.3580 (0.5068, 3.6390) /0.543	
>=50	2/ 66 (3%)	3/ 96 (3%)	0.9688 (0.1574, 5.9628) /0.973	-0.0947 (-5.5000, 5.3106) /0.973	0.9697 (0.1666, 5.6449) /0.973	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Insomnia <35	5/ 80 (6%)	2/ 80 (3%)	2.6000 (0.4894, 13.8141) /0.262	3.7500 (-2.5619, 10.0619) /0.244	2.5000 (0.4996, 12.5105) /0.265	0.837
35 - <50	5/162 (3%)	1/132 (<1%)	4.1720 (0.4814, 36.1585) /0.195	2.3288 (-0.7176, 5.3753) /0.134	4.0741 (0.4819, 34.4442) /0.197	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety <35	1/ 80 (1%)	3/ 80 (4%)	0.3249 (0.0331, 3.1918) /0.335	-2.5000 (-7.3227, 2.3227) /0.310	0.3333 (0.0354, 3.1369) /0.337	0.136
35 - <50	4/162 (2%)	1/132 (<1%)	3.3165 (0.3662, 30.0363) /0.286	1.7116 (-1.0989, 4.5220) /0.233	3.2593 (0.3687, 28.8100) /0.288	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	2/132 (2%)	0.8125 (0.1129, 5.8471) /0.837	-0.2806 (-2.9702, 2.4090) /0.838	0.8148 (0.1163, 5.7067) /0.837	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	0.326
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Acute stress disorder						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Depression <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Affect lability <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Drug abuse <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Irritability						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Mood altered						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Mood swings						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Panic disorder						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Thinking abnormal <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
<35	4/ 80 (5%)	6/ 80 (8%)	0.6491 (0.1760, 2.3938) /0.516	-2.5000 (-9.9914, 4.9914) /0.513	0.6667 (0.1955, 2.2731) /0.517	0.022
35 - <50	5/162 (3%)	3/132 (2%)	1.3694 (0.3212, 5.8391) /0.671	0.8137 (-2.8682, 4.4956) /0.665	1.3580 (0.3306, 5.5779) /0.671	
>=50	0/ 66	9/ 96 (9%)	<0.0001 (<0.0001, -) />0.999	-11.3455 (-36.4348, 13.7437) /0.375	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
<35	3/ 80 (4%)	5/ 80 (6%)	0.5844 (0.1349, 2.5323) /0.473	-2.5000 (-9.2429, 4.2429) /0.467	0.6000 (0.1483, 2.4268) /0.474	0.039
35 - <50	4/162 (2%)	1/132 (<1%)	3.3165 (0.3662, 30.0363) /0.286	1.7116 (-1.0989, 4.5220) /0.233	3.2593 (0.3687, 28.8100) /0.288	
>=50	0/ 66	5/ 96 (5%)	<0.0001 (<0.0001, -) />0.999	-7.3700 (-32.2589, 17.5190) /0.562	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Gout						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Hypercholesterolaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Hyperglycaemia <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Increased appetite						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Decreased appetite						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impaired fasting glucose						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Type 2 diabetes mellitus						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B12 deficiency						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	3/ 80 (4%)	2/ 80 (3%)	1.5195 (0.2470, 9.3470) /0.652	1.2500 (-4.1385, 6.6385) /0.649	1.5000 (0.2575, 8.7374) /0.652	0.992
35 - <50	8/162 (5%)	4/132 (3%)	1.6623 (0.4893, 5.6470) /0.415	1.9080 (-2.5286, 6.3445) /0.399	1.6296 (0.5017, 5.2929) /0.417	
>=50	4/ 66 (6%)	4/ 96 (4%)	1.4839 (0.3577, 6.1563) /0.587	1.8939 (-5.1143, 8.9022) /0.596	1.4545 (0.3771, 5.6108) /0.586	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood pressure increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Blood creatine phosphokinase increased						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.292
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Blood creatinine decreased						
<35	0/ 80	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Lipase increased						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Activated partial thromboplastin time prolonged <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	NC
>=50	0/ 66	0/ 96	NC	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Blood triglycerides increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Glycosylated haemoglobin increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Hepatic enzyme increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Lipids increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Pancreatic enzymes increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thyroxine free decreased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Vitamin D decreased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
<35	0/ 80	4/ 80 (5%)	<0.0001 (<0.0001, -) />0.999	-7.1707 (-30.0734, 15.7321) /0.539	<0.0001 (<0.0001, -) />0.999	0.020
35 - <50	5/162 (3%)	1/132 (<1%)	4.1720 (0.4814, 36.1585) /0.195	2.3288 (-0.7176, 5.3753) /0.134	4.0741 (0.4819, 34.4442) /0.197	
>=50	2/ 66 (3%)	3/ 96 (3%)	0.9688 (0.1574, 5.9628) /0.973	-0.0947 (-5.5000, 5.3106) /0.973	0.9697 (0.1666, 5.6449) /0.973	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Chalazion <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis allergic						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Eye pruritus						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Eyelid oedema <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Vision blurred <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Blepharitis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Cataract <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Cataract subcapsular						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctival haemorrhage						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Dry eye						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Eye pain						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Eye swelling						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Ocular hyperaemia						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	0.742
35 - <50	5/162 (3%)	3/132 (2%)	1.3694 (0.3212, 5.8391) /0.671	0.8137 (-2.8682, 4.4956) /0.665	1.3580 (0.3306, 5.5779) /0.671	
>=50	1/ 66 (2%)	2/ 96 (2%)	0.7231 (0.0642, 8.1413) /0.793	-0.5682 (-4.6728, 3.5364) /0.786	0.7273 (0.0673, 7.8574) /0.793	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Anaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	2/132 (2%)	0.8125 (0.1129, 5.8471) /0.837	-0.2806 (-2.9702, 2.4090) /0.838	0.8148 (0.1163, 5.7067) /0.837	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Lymphadenopathy <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Deficiency anaemia						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Eosinophilia						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
<hr/>						
Leukocytosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Microcytic anaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Preferred Term						

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.279
35 - <50	7/162 (4%)	1/132 (<1%)	5.9161 (0.7186, 48.7080) /0.098	3.5634 (0.1005, 7.0263) /0.044	5.7037 (0.7107, 45.7762) /0.101	
>=50	2/ 66 (3%)	3/ 96 (3%)	0.9688 (0.1574, 5.9628) /0.973	-0.0947 (-5.5000, 5.3106) /0.973	0.9697 (0.1666, 5.6449) /0.973	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Benign prostatic hyperplasia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysmenorrhoea <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Menorrhagia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Balanoposthitis						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cyst <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Breast pain <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysfunctional uterine bleeding						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Menometrorrhagi						
a						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Menstrual disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Metrorrhagia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	
Penile pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Scrotal mass						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Vaginal discharge						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal haemorrhage						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.013
35 - <50	7/162 (4%)	0/132	>999 (>999, >999) /NC	6.5203 (-11.1455, 24.1861) /0.469	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	4/ 96 (4%)	0.3538 (0.0387, 3.2391) /0.358	-2.6515 (-7.6177, 2.3147) /0.295	0.3636 (0.0416, 3.1809) /0.361	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Hypertension <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	4/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertensive crisis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Orthostatic hypotension						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Phlebitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Varicophlebitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Varicose vein						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Venous thrombosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35 - <50	5/162 (3%)	0/132	>999 (>999, >999) /NC	5.3329 (-12.2992, 22.9649) /0.553	>999 (>999, >999) /NC	
>=50	0/ 66	3/ 96 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-30.1817, 19.4415) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Pollakiuria						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Haematuria						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Micturition urgency						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Renal impairment <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Ear and labyrinth disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	2/132 (2%)	1.2264 (0.2019, 7.4501) /0.825	0.3367 (-2.6048, 3.2782) /0.822	1.2222 (0.2073, 7.2069) /0.825	
>=50	4/ 66 (6%)	0/ 96	>999 (>999, >999) /NC	8.1845 (-13.2031, 29.5721) /0.453	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Vertigo						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Deafness						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	
Ear discomfort						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Excessive cerumen production						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	2/ 80 (3%)	2/ 80 (3%)	1.0000 (0.1374, 7.2786) />0.999	<0.0001 (-4.8383, 4.8383) />0.999	1.0000 (0.1444, 6.9262) />0.999	0.544
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	0.995
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Lipoma <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
<hr/>						
Fibrous histiocytoma <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Knuckle pads						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Melanocytic naevus						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Cardiac disorders						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	4/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Bradycardia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Cardiovascular disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Palpitations						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Sinus tachycardia						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Ventricular extrasystoles						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Immune system disorders						
Any Event						
<35	1/ 80 (1%)	2/ 80 (3%)	0.4937 (0.0439, 5.5560) /0.568	-1.2500 (-5.4490, 2.9490) /0.560	0.5000 (0.0463, 5.4044) /0.568	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Seasonal allergy						
<35	0/ 80	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Allergy to animal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Mycotic allergy						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Endocrine disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypogonadism						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Hypothyroidism						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thyroid mass <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Social circumstances						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Menopause						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Stress at work						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Biliary tract disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion missed <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Dental implantation						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	39/ 80 (49%)	17/ 80 (21%)	3.5251 (1.7642, 7.0435) /<.001	27.5000 (13.3463, 41.6537) /<.001	2.2941 (1.4225, 3.6999) /<.001	0.164
35 - <50	86/162 (53%)	31/132 (23%)	3.6868 (2.2203, 6.1218) /<.001	29.6016 (19.0493, 40.1538) /<.001	2.2605 (1.6085, 3.1766) /<.001	
>=50	33/ 66 (50%)	33/ 96 (34%)	1.9091 (1.0062, 3.6222) /0.048	15.6250 (0.2699, 30.9801) /0.046	1.4545 (1.0079, 2.0992) /0.045	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	15/ 80 (19%)	12/ 80 (15%)	1.3077 (0.5692, 3.0042) /0.527	3.7500 (-7.8421, 15.3421) /0.526	1.2500 (0.6251, 2.4995) /0.528	0.894
35 - <50	30/162 (19%)	23/132 (17%)	1.0771 (0.5914, 1.9616) /0.808	1.0943 (-7.7178, 9.9064) /0.808	1.0628 (0.6497, 1.7386) /0.808	
>=50	13/ 66 (20%)	15/ 96 (16%)	1.3245 (0.5837, 3.0057) /0.501	4.0720 (-7.9620, 16.1060) /0.507	1.2606 (0.6429, 2.4717) /0.500	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.134
35 - <50	7/162 (4%)	3/132 (2%)	1.9419 (0.4922, 7.6615) /0.343	2.0483 (-1.9850, 6.0815) /0.320	1.9012 (0.5014, 7.2091) /0.345	
>=50	4/ 66 (6%)	0/ 96	>999 (>999, >999) /NC	8.1845 (-13.2031, 29.5721) /0.453	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.638
35 - <50	5/162 (3%)	1/132 (<1%)	4.1720 (0.4814, 36.1585) /0.195	2.3288 (-0.7176, 5.3753) /0.134	4.0741 (0.4819, 34.4442) /0.197	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Influenza						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	0/ 66	3/ 96 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-30.1817, 19.4415) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Respiratory tract infection						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	4/132 (3%)	0.4000 (0.0721, 2.2187) /0.295	-1.7957 (-5.1785, 1.5870) /0.298	0.4074 (0.0758, 2.1898) /0.295	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Bronchitis <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.054
35 - <50	4/162 (2%)	1/132 (<1%)	3.3165 (0.3662, 30.0363) /0.286	1.7116 (-1.0989, 4.5220) /0.233	3.2593 (0.3687, 28.8100) /0.288	
>=50	0/ 66	3/ 96 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-30.1817, 19.4415) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Pharyngitis <35	2/ 80 (3%)	1/ 80 (1%)	2.0256 (0.1800, 22.7973) /0.568	1.2500 (-2.9490, 5.4490) /0.560	2.0000 (0.1850, 21.6178) /0.568	0.633
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Lower respiratory tract infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Conjunctivitis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	
<hr/>						
Gonorrhoea <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Sinusitis <35	0/ 80	3/ 80 (4%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.200
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Viral upper respiratory tract infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tonsillitis <35	4/ 80 (5%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Rhinitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Acute sinusitis <35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Herpes simplex <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Hordeolum <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea versicolour						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Candida infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Cellulitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Fungal skin infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Herpes zoster <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	4/ 66 (6%)	0/ 96	>999 (>999, >999) /NC	8.1845 (-13.2031, 29.5721) /0.453	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychomycosis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Otitis media						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Proctitis gonococcal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tooth infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tracheitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Acarodermatitis <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Anal chlamydia infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	
Body tinea						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Cystitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Ear infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Injection site cellulitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media acute						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.323
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Staphylococcal infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Tooth abscess						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Urethritis gonococcal						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Vaginal infection						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Orchitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Urethritis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervicitis human papilloma virus						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
<hr/>						
Folliculitis <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Groin abscess <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Hepatitis A						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Infected bite						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver abscess <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Localised infection						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral candidiasis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Periodontitis						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Pertussis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Proctitis chlamydial						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Proctitis herpes						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Rotavirus infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tinea infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	28/ 80 (35%)	2/ 80 (3%)	21.0000 (4.7955, 91.9605) /<.001	32.5000 (21.5025, 43.4975) /<.001	14.0000 (3.4500, 56.8111) /<.001	0.500
35 - <50	58/162 (36%)	1/132 (<1%)	73.0577 (9.9520, 536.3176) /<.001	35.0449 (27.5156, 42.5742) /<.001	47.2593 (6.6344, 336.6461) /<.001	
>=50	20/ 66 (30%)	2/ 96 (2%)	20.4348 (4.5792, 91.1912) /<.001	28.2197 (16.7702, 39.6692) /<.001	14.5455 (3.5181, 60.1378) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injection site pain						
<35	23/ 80 (29%)	0/ 80	>999 (>999, >999) /NC	29.7847 (5.6465, 53.9229) /0.016	>999 (>999, >999) /NC	NC
35 - <50	50/162 (31%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	18/ 66 (27%)	0/ 96	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site nodule						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	>0.999
35 - <50	6/162 (4%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	>0.999
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Influenza like illness						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site bruising						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Pain						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Discomfort						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Oedema peripheral						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Chest discomfort						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Peripheral swelling						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Vessel puncture site pain						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	7/ 80 (9%)	3/ 80 (4%)	2.4612 (0.6131, 9.8801) /0.204	5.0000 (-2.4613, 12.4613) /0.189	2.3333 (0.6255, 8.7043) /0.207	0.613
35 - <50	12/162 (7%)	6/132 (5%)	1.6800 (0.6130, 4.6043) /0.313	2.8620 (-2.5131, 8.2370) /0.297	1.6296 (0.6286, 4.2249) /0.315	
>=50	4/ 66 (6%)	6/ 96 (6%)	0.9677 (0.2622, 3.5718) /0.961	-0.1894 (-7.7116, 7.3328) /0.961	0.9697 (0.2847, 3.3034) /0.961	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea <35	5/ 80 (6%)	1/ 80 (1%)	5.2667 (0.6012, 46.1344) /0.133	5.0000 (-0.8363, 10.8363) /0.093	5.0000 (0.5974, 41.8457) /0.138	0.792
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	0.068
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Toothache <35	0/ 80	0/ 80	NC	NC	NC	0.959
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	NC
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Vomiting						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
<hr/>						
Flatulence						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	
Gastritis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Enteritis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Food poisoning						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Inguinal hernia						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	
Odynophagia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis <35	0/ 80	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Dental caries <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Abdominal hernia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilic oesophagitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Functional gastrointestinal disorder						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Irritable bowel syndrome						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Pancreatitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis chronic						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis ulcerative						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Rectal haemorrhage						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	3/ 80 (4%)	1/ 80 (1%)	3.0779 (0.3133, 30.2376) /0.335	2.5000 (-2.3227, 7.3227) /0.310	3.0000 (0.3188, 28.2323) /0.337	0.179
35 - <50	14/162 (9%)	5/132 (4%)	2.4027 (0.8422, 6.8542) /0.101	4.8541 (-0.5614, 10.2696) /0.079	2.2815 (0.8436, 6.1703) /0.104	
>=50	4/ 66 (6%)	9/ 96 (9%)	0.6237 (0.1838, 2.1167) /0.449	-3.3144 (-11.5080, 4.8792) /0.428	0.6465 (0.2077, 2.0119) /0.451	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Back pain <35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.545
35 - <50	6/162 (4%)	1/132 (<1%)	5.0385 (0.5989, 42.3855) /0.137	2.9461 (-0.3166, 6.2088) /0.077	4.8889 (0.5960, 40.1032) /0.139	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Arthralgia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Myalgia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Pain in extremity						
<35	0/ 80	0/ 80	NC	NC	NC	0.998
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Musculoskeletal pain						
<35	0/ 80	0/ 80	NC	NC	NC	0.945
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	1/ 66 (2%)	2/ 96 (2%)	0.7231 (0.0642, 8.1413) /0.793	-0.5682 (-4.6728, 3.5364) /0.786	0.7273 (0.0673, 7.8574) /0.793	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Muscle spasms <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Muscle contracture <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Neck pain <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Tendonitis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteoarthritis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Arthropathy						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint effusion <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Myositis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Osteonecrosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Polyarthrititis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Spinal osteoarthritis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
<35	3/ 80 (4%)	2/ 80 (3%)	1.5195 (0.2470, 9.3470) /0.652	1.2500 (-4.1385, 6.6385) /0.649	1.5000 (0.2575, 8.7374) /0.652	0.588
35 - <50	10/162 (6%)	5/132 (4%)	1.6710 (0.5568, 5.0154) /0.360	2.3850 (-2.5486, 7.3185) /0.343	1.6296 (0.5711, 4.6505) /0.361	
>=50	1/ 66 (2%)	3/ 96 (3%)	0.4769 (0.0485, 4.6873) /0.525	-1.6098 (-6.1705, 2.9508) /0.489	0.4848 (0.0515, 4.5606) /0.527	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	0.543
35 - <50	5/162 (3%)	3/132 (2%)	1.3694 (0.3212, 5.8391) /0.671	0.8137 (-2.8682, 4.4956) /0.665	1.3580 (0.3306, 5.5779) /0.671	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Sciatica						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervicobrachial syndrome						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
----- Syncope <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Burning sensation						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Cerebrovascular accident						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysgeusia <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Intercostal neuralgia <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contractions involuntary						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuromuscular blockade						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Post-traumatic headache						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	2/ 80 (3%)	4/ 80 (5%)	0.4872 (0.0867, 2.7385) /0.414	-2.5000 (-8.3748, 3.3748) /0.404	0.5000 (0.0942, 2.6530) /0.416	0.059
35 - <50	4/162 (2%)	2/132 (2%)	1.6456 (0.2967, 9.1272) /0.569	0.9540 (-2.2167, 4.1246) /0.555	1.6296 (0.3032, 8.7592) /0.569	
>=50	0/ 66	6/ 96 (6%)	<0.0001 (<0.0001, -) />0.999	-8.3654 (-33.3026, 16.5718) /0.511	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Cough <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal pain						
<35	0/ 80	2/ 80 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Sinus congestion						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Respiratory disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Catarrh						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Productive cough						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Respiratory tract congestion						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract congestion <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Asthma <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Bronchospasm <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Lung disorder <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal septum deviation						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
<hr/>						
Pneumonitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Respiratory distress						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wheezing <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Rash						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Pruritus						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Eczema <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
<hr/>						
Urticaria <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Decubitus ulcer <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
<hr/>						
Intertrigo <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash erythematous						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash maculo-papular <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	7/ 80 (9%)	2/ 80 (3%)	3.7397 (0.7524, 18.5889) /0.107	6.2500 (-0.8242, 13.3242) /0.083	3.5000 (0.7499, 16.3360) /0.111	0.142
35 - <50	10/162 (6%)	3/132 (2%)	2.8289 (0.7623, 10.4989) /0.120	3.9001 (-0.5941, 8.3943) /0.089	2.7160 (0.7631, 9.6673) /0.123	
>=50	1/ 66 (2%)	4/ 96 (4%)	0.3538 (0.0387, 3.2391) /0.358	-2.6515 (-7.6177, 2.3147) /0.295	0.3636 (0.0416, 3.1809) /0.361	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain <35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epicondylitis <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exposure to communicable disease						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Procedural pain <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection related reaction						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Radius fracture <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Road traffic accident <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Hand fracture <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Upper limb fracture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Facial bones fracture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Humerus fracture						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Injury corneal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Joint dislocation						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament rupture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Meniscus injury <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Skin injury <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tendon rupture <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Tooth fracture <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<35	3/ 80 (4%)	2/ 80 (3%)	1.5195 (0.2470, 9.3470) /0.652	1.2500 (-4.1385, 6.6385) /0.649	1.5000 (0.2575, 8.7374) /0.652	0.999
35 - <50	7/162 (4%)	4/132 (3%)	1.4452 (0.4138, 5.0470) /0.564	1.2907 (-2.9936, 5.5750) /0.555	1.4259 (0.4266, 4.7664) /0.564	
>=50	2/ 66 (3%)	2/ 96 (2%)	1.4687 (0.2017, 10.6968) /0.704	0.9470 (-4.0796, 5.9735) /0.712	1.4545 (0.2101, 10.0688) /0.704	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Anxiety <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Depressed mood <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Depression <35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	0.085
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Drug abuse <35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Adjustment disorder						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depression suicidal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Drug dependence						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal behaviour						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	0.507
35 - <50	2/162 (1%)	5/132 (4%)	0.3175 (0.0606, 1.6636) /0.175	-2.5533 (-6.2272, 1.1206) /0.173	0.3259 (0.0643, 1.6529) /0.176	
>=50	2/ 66 (3%)	2/ 96 (2%)	1.4687 (0.2017, 10.6968) /0.704	0.9470 (-4.0796, 5.9735) /0.712	1.4545 (0.2101, 10.0688) /0.704	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Decreased appetite						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Dehydration						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Diabetes mellitus						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Diabetic ketoacidosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Hypokalaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Vitamin B6 deficiency						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	2/ 80 (3%)	2/ 80 (3%)	1.0000 (0.1374, 7.2786) />0.999	<0.0001 (-4.8383, 4.8383) />0.999	1.0000 (0.1444, 6.9262) />0.999	0.180
35 - <50	3/162 (2%)	4/132 (3%)	0.6038 (0.1327, 2.7466) /0.514	-1.1785 (-4.7647, 2.4078) /0.520	0.6111 (0.1392, 2.6824) /0.514	
>=50	4/ 66 (6%)	1/ 96 (1%)	6.1290 (0.6693, 56.1251) /0.109	5.0189 (-1.0853, 11.1232) /0.107	5.8182 (0.6651, 50.8951) /0.112	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Alanine aminotransferase increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Blood creatine phosphokinase increased						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.218
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Creatinine renal clearance decreased						
<35	1/ 80 (1%)	1/ 80 (1%)	1.0000 (0.0615, 16.2696) />0.999	<0.0001 (-3.4430, 3.4430) />0.999	1.0000 (0.0636, 15.7121) />0.999	0.443
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Blood glucose increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
ECG signs of ventricular hypertrophy						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neisseria test positive						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Eye disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	2/ 96 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3571 (-29.1616, 20.4474) /0.731	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lacrimation increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Vitreous haematoma						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	2/132 (2%)	0.8125 (0.1129, 5.8471) /0.837	-0.2806 (-2.9702, 2.4090) /0.838	0.8148 (0.1163, 5.7067) /0.837	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Anaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia folate deficiency						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Thrombocytopeni a						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.043
35 - <50	2/162 (1%)	2/132 (2%)	0.8125 (0.1129, 5.8471) /0.837	-0.2806 (-2.9702, 2.4090) /0.838	0.8148 (0.1163, 5.7067) /0.837	
>=50	3/ 66 (5%)	0/ 96	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Benign prostatic hyperplasia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
<hr/>						
Menorrhagia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Balanoposthitis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Cervical dysplasia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Adenomyosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Breast mass						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital erythema						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Vascular disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	0.995
35 - <50	3/162 (2%)	2/132 (2%)	1.2264 (0.2019, 7.4501) /0.825	0.3367 (-2.6048, 3.2782) /0.822	1.2222 (0.2073, 7.2069) /0.825	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Hypertension <35	0/ 80	0/ 80	NC	NC	NC	0.960
35 - <50	3/162 (2%)	1/132 (<1%)	2.4717 (0.2541, 24.0434) /0.436	1.0943 (-1.4548, 3.6434) /0.400	2.4444 (0.2573, 23.2264) /0.437	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Deep vein thrombosis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Renal and urinary disorders						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.147
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	2/ 96 (2%)	0.7231 (0.0642, 8.1413) /0.793	-0.5682 (-4.6728, 3.5364) /0.786	0.7273 (0.0673, 7.8574) /0.793	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Renal impairment <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Renal colic <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Urethral discharge						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Anogenital warts						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Basal cell carcinoma						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin papilloma <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Squamous cell carcinoma of skin						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Allergy to animal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Drug hypersensitivity						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Endocrine disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypothyroidism <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis acute						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion spontaneous						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	5/ 80 (6%)	2/ 80 (3%)	2.6000 (0.4894, 13.8141) /0.262	3.7500 (-2.5619, 10.0619) /0.244	2.5000 (0.4996, 12.5105) /0.265	0.691
35 - <50	18/162 (11%)	12/132 (9%)	1.2500 (0.5790, 2.6985) /0.570	2.0202 (-4.8697, 8.9101) /0.566	1.2222 (0.6110, 2.4449) /0.571	
>=50	4/ 66 (6%)	5/ 96 (5%)	1.1742 (0.3032, 4.5467) /0.816	0.8523 (-6.4205, 8.1250) /0.818	1.1636 (0.3245, 4.1722) /0.816	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	2/132 (2%)	0.8125 (0.1129, 5.8471) /0.837	-0.2806 (-2.9702, 2.4090) /0.838	0.8148 (0.1163, 5.7067) /0.837	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Viral infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Anal abscess						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hepatitis A						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Appendicitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Gastroenteritis Escherichia coli						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	NC
>=50	0/ 66	0/ 96	NC	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	4/ 80 (5%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35 - <50	7/162 (4%)	0/132	>999 (>999, >999) /NC	6.5203 (-11.1455, 24.1861) /0.469	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35 - <50	7/162 (4%)	0/132	>999 (>999, >999) /NC	6.5203 (-11.1455, 24.1861) /0.469	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Injection site induration <35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.167
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Diarrhoea						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Nausea						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vomiting						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	
Abdominal pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Colitis <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Pancreatitis acute						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Arthralgia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	
Rhabdomyolysis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Nervous system disorders						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Headache						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Seizure <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Eye injury <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Depression <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Anxiety disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertriglyceridaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	7/162 (4%)	2/132 (2%)	2.9355 (0.5994, 14.3756) /0.184	2.8058 (-0.9553, 6.5670) /0.144	2.8519 (0.6025, 13.4980) /0.186	
>=50	0/ 66	3/ 96 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3701 (-30.1817, 19.4415) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Blood creatine phosphokinase increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Blood triglycerides increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood phosphorus decreased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood triglycerides						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Liver function test abnormal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood and lymphatic system disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Anaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Ovarian cyst ruptured						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Chronic kidney disease						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Anogenital warts						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Papillary thyroid cancer						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Seminoma						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Overall						
Any Event						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.209
35 - <50	4/162 (2%)	3/132 (2%)	1.0886 (0.2393, 4.9521) /0.913	0.1964 (-3.2927, 3.6856) /0.912	1.0864 (0.2475, 4.7688) /0.913	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis A						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	
Acute hepatitis B						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis C						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis acute						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	0.375
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Lipase increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Blood bilirubin increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Neutropenia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Squamous cell carcinoma						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Hyperbilirubinaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 5

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 5

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS

Maximum Toxicity Grade= 5

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	34/ 99 (34%)	38/104 (37%)	0.9085 (0.5109, 1.6156) /0.744	-2.1950 (-15.3535, 10.9634) /0.744	0.9399 (0.6480, 1.3634) /0.744	0.664
Male	67/209 (32%)	77/204 (38%)	0.7782 (0.5187, 1.1675) /0.226	-5.6877 (-14.8682, 3.4928) /0.225	0.8493 (0.6519, 1.1066) /0.226	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
Female	32/ 99 (32%)	35/104 (34%)	0.9416 (0.5243, 1.6910) /0.840	-1.3306 (-14.2672, 11.6060) /0.840	0.9605 (0.6487, 1.4221) /0.840	0.349
Male	93/209 (44%)	76/204 (37%)	1.3503 (0.9109, 2.0017) /0.135	7.2427 (-2.2131, 16.6985) /0.133	1.1944 (0.9454, 1.5089) /0.136	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
Female	9/ 99 (9%)	7/104 (7%)	1.3857 (0.4954, 3.8758) /0.534	2.3601 (-5.0733, 9.7936) /0.534	1.3506 (0.5231, 3.4876) /0.535	0.505
Male	31/209 (15%)	32/204 (16%)	0.9361 (0.5474, 1.6008) /0.809	-0.8537 (-7.7909, 6.0834) /0.809	0.9456 (0.6001, 1.4899) /0.809	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Upper respiratory tract infection						
Female	6/ 99 (6%)	8/104 (8%)	0.7742 (0.2587, 2.3171) /0.647	-1.6317 (-8.5829, 5.3195) /0.645	0.7879 (0.2835, 2.1895) /0.648	0.463
Male	19/209 (9%)	15/204 (7%)	1.2600 (0.6218, 2.5533) /0.521	1.7380 (-3.5553, 7.0312) /0.520	1.2364 (0.6462, 2.3657) /0.522	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza Female	6/ 99 (6%)	3/104 (3%)	2.1720 (0.5280, 8.9344) /0.282	3.1760 (-2.5195, 8.8715) /0.274	2.1010 (0.5402, 8.1721) /0.284	0.765
Male	10/209 (5%)	6/204 (3%)	1.6583 (0.5914, 4.6499) /0.336	1.8435 (-1.8645, 5.5515) /0.330	1.6268 (0.6023, 4.3937) /0.337	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
Female	3/ 99 (3%)	4/104 (4%)	0.7813 (0.1704, 3.5825) /0.751	-0.8159 (-5.8221, 4.1904) /0.749	0.7879 (0.1809, 3.4316) /0.751	0.815
Male	7/209 (3%)	7/204 (3%)	0.9752 (0.3359, 2.8315) /0.963	-0.0821 (-3.5735, 3.4093) /0.963	0.9761 (0.3486, 2.7333) /0.963	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Respiratory tract infection viral						
Female	1/ 99 (1%)	2/104 (2%)	0.5204 (0.0464, 5.8315) /0.596	-0.9130 (-4.2064, 2.3804) /0.587	0.5253 (0.0484, 5.7016) /0.597	0.992
Male	6/209 (3%)	11/204 (5%)	0.5186 (0.1881, 1.4296) /0.204	-2.5213 (-6.3595, 1.3168) /0.198	0.5324 (0.2007, 1.4127) /0.205	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis Female	3/ 99 (3%)	2/104 (2%)	1.5937 (0.2606, 9.7460) /0.614	1.1072 (-3.1787, 5.3931) /0.613	1.5758 (0.2690, 9.2316) /0.614	0.783
Male	6/209 (3%)	5/204 (2%)	1.1764 (0.3533, 3.9166) /0.791	0.4198 (-2.6830, 3.5226) /0.791	1.1713 (0.3632, 3.7778) /0.791	
Urinary tract infection Female	6/ 99 (6%)	4/104 (4%)	1.6129 (0.4412, 5.8962) /0.470	2.2145 (-3.7648, 8.1937) /0.468	1.5758 (0.4584, 5.4173) /0.470	0.840
Male	4/209 (2%)	2/204 (<1%)	1.9707 (0.3570, 10.8794) /0.436	0.9335 (-1.3640, 3.2310) /0.426	1.9522 (0.3615, 10.5414) /0.437	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
Female	0/ 99	3/104 (3%)	<0.0001 (<0.0001, -) />0.999	-5.1377 (-25.6021, 15.3266) /0.623	<0.0001 (<0.0001, -) />0.999	0.085
Male	5/209 (2%)	6/204 (3%)	0.8088 (0.2429, 2.6930) /0.730	-0.5488 (-3.6581, 2.5604) /0.729	0.8134 (0.2522, 2.6235) /0.730	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis Female	1/ 99 (1%)	4/104 (4%)	0.2551 (0.0280, 2.3230) /0.225	-2.8361 (-7.0241, 1.3520) /0.184	0.2626 (0.0299, 2.3093) /0.228	0.376
Male	4/209 (2%)	5/204 (2%)	0.7766 (0.2056, 2.9339) /0.709	-0.5371 (-3.3572, 2.2829) /0.709	0.7809 (0.2127, 2.8668) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
Female	4/ 99 (4%)	3/104 (3%)	1.4175 (0.3091, 6.5004) /0.653	1.1558 (-3.8833, 6.1948) /0.653	1.4007 (0.3216, 6.1006) /0.654	0.815
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Conjunctivitis						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	6/209 (3%)	3/204 (1%)	1.9803 (0.4885, 8.0269) /0.339	1.4002 (-1.4022, 4.2027) /0.327	1.9522 (0.4949, 7.7010) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	6/209 (3%)	3/204 (1%)	1.9803 (0.4885, 8.0269) /0.339	1.4002 (-1.4022, 4.2027) /0.327	1.9522 (0.4949, 7.7010) /0.339	
Oral herpes						
Female	2/ 99 (2%)	2/104 (2%)	1.0515 (0.1452, 7.6129) /0.960	0.0971 (-3.7300, 3.9243) /0.960	1.0505 (0.1509, 7.3142) /0.960	0.721
Male	2/209 (<1%)	3/204 (1%)	0.6473 (0.1070, 3.9150) /0.636	-0.5137 (-2.6280, 1.6007) /0.634	0.6507 (0.1099, 3.8539) /0.636	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.267
Male	5/209 (2%)	2/204 (<1%)	2.4755 (0.4748, 12.9069) /0.282	1.4120 (-1.0619, 3.8858) /0.263	2.4402 (0.4789, 12.4350) /0.283	
Syphilis Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	7/204 (3%)	0.2719 (0.0558, 1.3248) /0.107	-2.4744 (-5.2996, 0.3508) /0.086	0.2789 (0.0586, 1.3266) /0.109	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	5/209 (2%)	3/204 (1%)	1.6422 (0.3873, 6.9626) /0.501	0.9218 (-1.7279, 3.5714) /0.495	1.6268 (0.3939, 6.7188) /0.501	
Chlamydial infection						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	5/209 (2%)	2/204 (<1%)	2.4755 (0.4748, 12.9069) /0.282	1.4120 (-1.0619, 3.8858) /0.263	2.4402 (0.4789, 12.4350) /0.283	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis viral						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	5/209 (2%)	1/204 (<1%)	4.9755 (0.5762, 42.9626) /0.145	1.9021 (-0.3805, 4.1848) /0.102	4.8804 (0.5751, 41.4121) /0.146	
Tonsillitis						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	4/209 (2%)	2/204 (<1%)	1.9707 (0.3570, 10.8794) /0.436	0.9335 (-1.3640, 3.2310) /0.426	1.9522 (0.3615, 10.5414) /0.437	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.142
Male	3/209 (1%)	1/204 (<1%)	2.9563 (0.3050, 28.6570) /0.350	0.9452 (-0.9307, 2.8211) /0.323	2.9282 (0.3071, 27.9197) /0.350	
Furuncle Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute sinusitis						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.294
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Herpes simplex						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.294
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Tinea cruris Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea versicolour						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Candida infection						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chronic tonsillitis						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Fungal skin infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Genital herpes simplex						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Impetigo						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Onychomycosis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Paronychia						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis gonococcal						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Pulpitis dental						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tracheitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Urethritis chlamydial						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Amoebiasis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal infection Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Anorectal human papilloma virus infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Clostridium difficile colitis Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis bacterial						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Cystitis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Enteritis infectious Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epididymitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Gastric infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Gastrointestinal viral infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Herpes virus infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Infection parasitic Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site cellulitis						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Laryngitis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal herpes						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Oropharyngeal gonococcal infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis media acute						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Pneumonia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia mycoplasmal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Post procedural infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Primary syphilis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Secondary syphilis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted disease						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Skin candida						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Staphylococcal skin infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Tinea pedis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tongue fungal infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Tooth abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureaplasma infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Urethritis gonococcal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal infection						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Viral infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral tonsillitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Vulvovaginal candidiasis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginitis trichomonal Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
Female	46/ 99 (46%)	7/104 (7%)	12.0270 (5.0753, 28.5005) /<.001	39.7339 (28.7927, 50.6751) /<.001	6.9033 (3.2739, 14.5563) /<.001	0.646
Male	89/209 (43%)	10/204 (5%)	14.3883 (7.2011, 28.7490) /<.001	37.6818 (30.3525, 45.0110) /<.001	8.6871 (4.6518, 16.2227) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
Female	41/ 99 (41%)	0/104	>999 (>999, >999) /NC	41.8321 (20.2903, 63.3740) /<.001	>999 (>999, >999) /NC	NC
Male	89/209 (43%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site nodule						
Female	13/ 99 (13%)	0/104	>999 (>999, >999) /NC	14.9229 (-5.6695, 35.5153) /0.156	>999 (>999, >999) /NC	NC
Male	20/209 (10%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Fatigue						
Female	6/ 99 (6%)	2/104 (2%)	3.2903 (0.6480, 16.7061) /0.151	4.1375 (-1.2530, 9.5281) /0.132	3.1515 (0.6514, 15.2464) /0.154	0.720
Male	14/209 (7%)	3/204 (1%)	4.8102 (1.3612, 16.9991) /0.015	5.2280 (1.4576, 8.9984) /0.007	4.5550 (1.3288, 15.6140) /0.016	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
Female	5/ 99 (5%)	2/104 (2%)	2.7128 (0.5140, 14.3187) /0.240	3.1274 (-1.9297, 8.1845) /0.225	2.6263 (0.5215, 13.2252) /0.242	0.755
Male	12/209 (6%)	6/204 (3%)	2.0102 (0.7398, 5.4622) /0.171	2.8005 (-1.1140, 6.7149) /0.161	1.9521 (0.7469, 5.1025) /0.172	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
Female	9/ 99 (9%)	0/104	>999 (>999, >999) /NC	11.0748 (-9.2892, 31.4389) /0.286	>999 (>999, >999) /NC	>0.999
Male	11/209 (5%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injection site swelling						
Female	5/ 99 (5%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	11/209 (5%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site erythema						
Female	6/ 99 (6%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	6/209 (3%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
Female	2/ 99 (2%)	2/104 (2%)	1.0515 (0.1452, 7.6129) /0.960	0.0971 (-3.7300, 3.9243) /0.960	1.0505 (0.1509, 7.3142) /0.960	0.364
Male	4/209 (2%)	1/204 (<1%)	3.9610 (0.4389, 35.7437) /0.220	1.4237 (-0.6665, 3.5139) /0.182	3.9043 (0.4401, 34.6355) /0.221	
Injection site bruising						
Female	3/ 99 (3%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	5/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pruritus						
Female	5/ 99 (5%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Asthenia						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	4/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	5/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pain						
Female	3/ 99 (3%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site haematoma						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.971
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.317
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cyst						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Discomfort						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Feeling of body temperature change						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Injection site anaesthesia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discolouration						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site discomfort						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Oedema peripheral						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	17/ 99 (17%)	9/104 (9%)	2.1883 (0.9258, 5.1729) /0.074	8.5179 (-0.6684, 17.7042) /0.069	1.9843 (0.9283, 4.2414) /0.077	0.563
Male	31/209 (15%)	20/204 (10%)	1.6022 (0.8805, 2.9157) /0.123	5.0286 (-1.2857, 11.3429) /0.119	1.5129 (0.8923, 2.5652) /0.124	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea Female	5/ 99 (5%)	3/104 (3%)	1.7908 (0.4164, 7.7007) /0.434	2.1659 (-3.2151, 7.5469) /0.430	1.7508 (0.4297, 7.1331) /0.434	0.409
Male	9/209 (4%)	10/204 (5%)	0.8730 (0.3472, 2.1949) /0.773	-0.5957 (-4.6395, 3.4481) /0.773	0.8785 (0.3645, 2.1171) /0.773	
Nausea Female	4/ 99 (4%)	1/104 (<1%)	4.3368 (0.4762, 39.4928) /0.193	3.0789 (-1.2295, 7.3872) /0.161	4.2020 (0.4779, 36.9484) /0.196	0.202
Male	6/209 (3%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation Female	3/ 99 (3%)	3/104 (3%)	1.0521 (0.2073, 5.3403) /0.951	0.1457 (-4.5180, 4.8093) /0.951	1.0505 (0.2171, 5.0821) /0.951	0.276
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Toothache Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	0.242
Male	1/209 (<1%)	3/204 (1%)	0.3221 (0.0332, 3.1224) /0.328	-0.9921 (-2.8905, 0.9062) /0.306	0.3254 (0.0341, 3.1022) /0.329	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	0.966
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Gastrooesophageal reflux disease						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	4/209 (2%)	1/204 (<1%)	3.9610 (0.4389, 35.7437) /0.220	1.4237 (-0.6665, 3.5139) /0.182	3.9043 (0.4401, 34.6355) /0.221	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	3/209 (1%)	2/204 (<1%)	1.4709 (0.2432, 8.8955) /0.674	0.4550 (-1.6494, 2.5594) /0.672	1.4641 (0.2472, 8.6713) /0.674	
Vomiting						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.142
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.317
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Flatulence						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Abdominal pain upper						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aphthous ulcer						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastritis						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal distension						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal fissure						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal pruritus						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Anal skin tags						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal discomfort						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chronic gastritis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphagia Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Enteritis Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epigastric discomfort						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Food poisoning						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Haemorrhoids thrombosed						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Lip dry						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip swelling						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Mouth ulceration						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Oral disorder						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Oral pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Proctitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Steatorrhoea						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Tongue ulceration						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth impacted						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Umbilical hernia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
Female	13/ 99 (13%)	8/104 (8%)	1.8140 (0.7175, 4.5863) /0.208	5.4390 (-2.9568, 13.8348) /0.204	1.7071 (0.7395, 3.9409) /0.210	0.964
Male	34/209 (16%)	19/204 (9%)	1.8917 (1.0400, 3.4409) /0.037	6.9542 (0.5557, 13.3528) /0.033	1.7467 (1.0310, 2.9592) /0.038	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain Female	3/ 99 (3%)	3/104 (3%)	1.0521 (0.2073, 5.3403) /0.951	0.1457 (-4.5180, 4.8093) /0.951	1.0505 (0.2171, 5.0821) /0.951	0.824
Male	8/209 (4%)	6/204 (3%)	1.3134 (0.4476, 3.8543) /0.620	0.8866 (-2.5979, 4.3711) /0.618	1.3014 (0.4596, 3.6849) /0.620	
Arthralgia Female	1/ 99 (1%)	2/104 (2%)	0.5204 (0.0464, 5.8315) /0.596	-0.9130 (-4.2064, 2.3804) /0.587	0.5253 (0.0484, 5.7016) /0.597	0.772
Male	4/209 (2%)	5/204 (2%)	0.7766 (0.2056, 2.9339) /0.709	-0.5371 (-3.3572, 2.2829) /0.709	0.7809 (0.2127, 2.8668) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.300
Male	6/209 (3%)	2/204 (<1%)	2.9852 (0.5954, 14.9661) /0.184	1.8904 (-0.7465, 4.5273) /0.160	2.9282 (0.5980, 14.3397) /0.185	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
Female	1/ 99 (1%)	3/104 (3%)	0.3435 (0.0351, 3.3592) /0.358	-1.8745 (-5.6464, 1.8974) /0.330	0.3502 (0.0370, 3.3103) /0.360	0.667
Male	2/209 (<1%)	3/204 (1%)	0.6473 (0.1070, 3.9150) /0.636	-0.5137 (-2.6280, 1.6007) /0.634	0.6507 (0.1099, 3.8539) /0.636	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
Female	0/ 99	2/104 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1992 (-24.6656, 16.2672) /0.688	<0.0001 (<0.0001, -) />0.999	0.140
Male	3/209 (1%)	3/204 (1%)	0.9757 (0.1946, 4.8914) /0.976	-0.0352 (-2.3436, 2.2733) /0.976	0.9761 (0.1993, 4.7799) /0.976	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.971
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint swelling						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.294
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Muscle contracture						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Neck pain Female	3/ 99 (3%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Spinal pain Female	0/ 99	0/104	NC	NC	NC	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tendonitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Bursitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Foot deformity						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Intervertebral disc protrusion						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Musculoskeletal chest pain						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Osteoarthritis						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteopenia						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Arthritis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Costochondritis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dupuytren's contracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exostosis Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Flank pain Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle tightness						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Musculoskeletal discomfort						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Patellofemoral pain syndrome						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Scoliosis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovial cyst Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Temporomandibular joint syndrome Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tenosynovitis Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
Female	18/ 99 (18%)	7/104 (7%)	3.0794 (1.2253, 7.7389) /0.017	11.4510 (2.4560, 20.4461) /0.013	2.7013 (1.1796, 6.1858) /0.019	0.372
Male	30/209 (14%)	17/204 (8%)	1.8436 (0.9826, 3.4591) /0.057	6.0207 (-0.0604, 12.1019) /0.052	1.7225 (0.9811, 3.0241) /0.058	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache Female	12/ 99 (12%)	5/104 (5%)	2.7310 (0.9253, 8.0605) /0.069	7.3135 (-0.3178, 14.9448) /0.060	2.5212 (0.9217, 6.8968) /0.072	0.708
Male	14/209 (7%)	7/204 (3%)	2.0205 (0.7983, 5.1140) /0.138	3.2672 (-0.9432, 7.4776) /0.128	1.9521 (0.8044, 4.7373) /0.139	
Dizziness Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	0.954
Male	7/209 (3%)	3/204 (1%)	2.3218 (0.5920, 9.1053) /0.227	1.8787 (-1.0672, 4.8246) /0.211	2.2775 (0.5971, 8.6864) /0.228	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.570
Male	3/209 (1%)	1/204 (<1%)	2.9563 (0.3050, 28.6570) /0.350	0.9452 (-0.9307, 2.8211) /0.323	2.9282 (0.3071, 27.9197) /0.350	
Sciatica Female	3/ 99 (3%)	1/104 (<1%)	3.2187 (0.3292, 31.4746) /0.315	2.0688 (-1.7938, 5.9313) /0.294	3.1515 (0.3334, 29.7926) /0.317	0.353
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.317
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Neuralgia Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.053
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervicobrachial syndrome						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hypoaesthesia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Presyncope						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Somnolence						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Anterograde amnesia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Autonomic nervous system imbalance						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Cerebral cyst						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cognitive disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Disturbance in attention						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Dysaesthesia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dystonia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Essential tremor						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Facial paralysis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Loss of consciousness						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Memory impairment						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post herpetic neuralgia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tension headache						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	12/ 99 (12%)	6/104 (6%)	2.2529 (0.8111, 6.2578) /0.119	6.3520 (-1.4847, 14.1886) /0.112	2.1010 (0.8203, 5.3815) /0.122	0.175
Male	18/209 (9%)	18/204 (9%)	0.9738 (0.4915, 1.9295) /0.939	-0.2111 (-5.6531, 5.2309) /0.939	0.9761 (0.5229, 1.8221) /0.939	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough Female	8/ 99 (8%)	5/104 (5%)	1.7407 (0.5495, 5.5140) /0.346	3.2731 (-3.4890, 10.0352) /0.343	1.6808 (0.5691, 4.9640) /0.347	0.492
Male	6/209 (3%)	6/204 (3%)	0.9754 (0.3093, 3.0755) /0.966	-0.0704 (-3.3108, 3.1701) /0.966	0.9761 (0.3201, 2.9767) /0.966	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
Female	1/ 99 (1%)	2/104 (2%)	0.5204 (0.0464, 5.8315) /0.596	-0.9130 (-4.2064, 2.3804) /0.587	0.5253 (0.0484, 5.7016) /0.597	0.558
Male	8/209 (4%)	7/204 (3%)	1.1201 (0.3986, 3.1477) /0.830	0.3964 (-3.2100, 4.0028) /0.829	1.1155 (0.4121, 3.0198) /0.830	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal congestion						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.005
Male	0/209	4/204 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Sinus congestion						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.738
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
Female	2/ 99 (2%)	2/104 (2%)	1.0515 (0.1452, 7.6129) /0.960	0.0971 (-3.7300, 3.9243) /0.960	1.0505 (0.1509, 7.3142) /0.960	>0.999
Male	0/209	0/204	NC	NC	NC	
Rhinorrhoea						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.017
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphonia Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.047
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Catarrh Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspnoea						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Rhinitis allergic						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Emphysema						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nasal obstruction						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Productive cough						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Pulmonary mass						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Reflux laryngitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Respiratory tract congestion						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Sleep apnoea syndrome						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
Female	11/ 99 (11%)	6/104 (6%)	2.0417 (0.7249, 5.7505) /0.177	5.3419 (-2.3004, 12.9841) /0.171	1.9259 (0.7405, 5.0093) /0.179	0.583
Male	20/209 (10%)	14/204 (7%)	1.4361 (0.7046, 2.9271) /0.319	2.7066 (-2.5794, 7.9926) /0.316	1.3944 (0.7242, 2.6849) /0.320	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
Female	3/ 99 (3%)	3/104 (3%)	1.0521 (0.2073, 5.3403) /0.951	0.1457 (-4.5180, 4.8093) /0.951	1.0505 (0.2171, 5.0821) /0.951	0.132
Male	7/209 (3%)	1/204 (<1%)	7.0347 (0.8577, 57.6951) /0.069	2.8591 (0.2383, 5.4799) /0.033	6.8325 (0.8482, 55.0414) /0.071	
Pruritus						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.298
Male	4/209 (2%)	3/204 (1%)	1.3073 (0.2889, 5.9151) /0.728	0.4433 (-2.0425, 2.9290) /0.727	1.3014 (0.2949, 5.7427) /0.728	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acne						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Eczema						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	3/209 (1%)	1/204 (<1%)	2.9563 (0.3050, 28.6570) /0.350	0.9452 (-0.9307, 2.8211) /0.323	2.9282 (0.3071, 27.9197) /0.350	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Rash pruritic Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.971
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Alopecia Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.317
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.294
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash generalised						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.294
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoeic dermatitis						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Ecchymosis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Dermatitis acneiform Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis contact						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nail bed bleeding						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neurodermatitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Onychoclasia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Photosensitivity reaction						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Pruritus generalised						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Purpura Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Sebaceous hyperplasia Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoea						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Skin fissures						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin lesion						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Skin mass						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Stasis dermatitis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Urticaria						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	5/ 99 (5%)	3/104 (3%)	1.7908 (0.4164, 7.7007) /0.434	2.1659 (-3.2151, 7.5469) /0.430	1.7508 (0.4297, 7.1331) /0.434	0.361
Male	14/209 (7%)	16/204 (8%)	0.8436 (0.4006, 1.7765) /0.654	-1.1446 (-6.1544, 3.8652) /0.654	0.8541 (0.4280, 1.7042) /0.654	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament sprain						
Female	3/ 99 (3%)	1/104 (<1%)	3.2187 (0.3292, 31.4746) /0.315	2.0688 (-1.7938, 5.9313) /0.294	3.1515 (0.3334, 29.7926) /0.317	0.353
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Muscle strain						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	4/204 (2%)	0.4831 (0.0875, 2.6669) /0.404	-1.0038 (-3.3194, 1.3117) /0.396	0.4880 (0.0904, 2.6354) /0.404	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.198
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Arthropod bite Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	
Bone contusion						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Epicondylitis						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Exposure to communicable disease						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Procedural pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Soft tissue injury						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Animal bite						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Buttock injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection related reaction						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural complication						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Radius fracture						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Road traffic accident						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin abrasion						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Splinter						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
Female	2/ 99 (2%)	4/104 (4%)	0.5155 (0.0923, 2.8792) /0.450	-1.8260 (-6.4456, 2.7937) /0.439	0.5253 (0.0984, 2.8040) /0.451	0.182
Male	18/209 (9%)	10/204 (5%)	1.8283 (0.8228, 4.0625) /0.139	3.7105 (-1.1108, 8.5318) /0.131	1.7569 (0.8311, 3.7141) /0.140	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia Female	2/ 99 (2%)	2/104 (2%)	1.0515 (0.1452, 7.6129) /0.960	0.0971 (-3.7300, 3.9243) /0.960	1.0505 (0.1509, 7.3142) /0.960	0.252
Male	9/209 (4%)	2/204 (<1%)	4.5450 (0.9699, 21.2983) /0.055	3.3258 (0.2595, 6.3921) /0.034	4.3923 (0.9607, 20.0824) /0.056	
Anxiety Female	0/ 99	0/104	NC	NC	NC	NC
Male	6/209 (3%)	4/204 (2%)	1.4778 (0.4108, 5.3159) /0.550	0.9100 (-2.0472, 3.8672) /0.546	1.4641 (0.4193, 5.1121) /0.550	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.142
Male	3/209 (1%)	1/204 (<1%)	2.9563 (0.3050, 28.6570) /0.350	0.9452 (-0.9307, 2.8211) /0.323	2.9282 (0.3071, 27.9197) /0.350	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.179
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	
Depressed mood						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute stress disorder						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Depression						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Affect lability Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Irritability						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mood altered						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Mood swings						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Panic disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Tension						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thinking abnormal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
Female	6/ 99 (6%)	4/104 (4%)	1.6129 (0.4412, 5.8962) /0.470	2.2145 (-3.7648, 8.1937) /0.468	1.5758 (0.4584, 5.4173) /0.470	0.017
Male	3/209 (1%)	14/204 (7%)	0.1976 (0.0559, 0.6985) /0.012	-5.4273 (-9.2531, -1.6016) /0.005	0.2092 (0.0610, 0.7170) /0.013	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
Female	5/ 99 (5%)	2/104 (2%)	2.7128 (0.5140, 14.3187) /0.240	3.1274 (-1.9297, 8.1845) /0.225	2.6263 (0.5215, 13.2252) /0.242	0.016
Male	2/209 (<1%)	9/204 (4%)	0.2093 (0.0447, 0.9810) /0.047	-3.4548 (-6.5666, -0.3430) /0.030	0.2169 (0.0474, 0.9917) /0.049	
Gout						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperglycaemi ^a						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Increased appetite						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Decreased appetite						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impaired fasting glucose						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Type 2 diabetes mellitus						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B12 deficiency						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	5/ 99 (5%)	1/104 (<1%)	5.4787 (0.6286, 47.7525) /0.124	4.0890 (-0.6148, 8.7927) /0.088	5.2525 (0.6246, 44.1693) /0.127	0.135
Male	10/209 (5%)	9/204 (4%)	1.0888 (0.4331, 2.7374) /0.857	0.3729 (-3.6662, 4.4121) /0.856	1.0845 (0.4500, 2.6137) /0.857	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood pressure increased						
Female	3/ 99 (3%)	1/104 (<1%)	3.2187 (0.3292, 31.4746) /0.315	2.0688 (-1.7938, 5.9313) /0.294	3.1515 (0.3334, 29.7926) /0.317	0.127
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Alanine aminotransferase increased						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	3/209 (1%)	1/204 (<1%)	2.9563 (0.3050, 28.6570) /0.350	0.9452 (-0.9307, 2.8211) /0.323	2.9282 (0.3071, 27.9197) /0.350	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine decreased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Aspartate aminotransferase increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Lipase increased						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Activated partial thromboplastin time prolonged						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Blood cholesterol increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood triglycerides increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Glycosylated haemoglobin increased						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic enzyme increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Lipids increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatic enzymes increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Thyroxine free decreased						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D decreased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Weight decreased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye disorders						
Any Event						
Female	3/ 99 (3%)	2/104 (2%)	1.5937 (0.2606, 9.7460) /0.614	1.1072 (-3.1787, 5.3931) /0.613	1.5758 (0.2690, 9.2316) /0.614	0.418
Male	4/209 (2%)	6/204 (3%)	0.6439 (0.1790, 2.3162) /0.500	-1.0273 (-3.9982, 1.9435) /0.498	0.6507 (0.1864, 2.2720) /0.501	
Chalazion						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis allergic						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Eye pruritus						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid oedema						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Vision blurred						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cataract Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract subcapsular Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Conjunctival haemorrhage Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry eye						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Eye pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye swelling						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Ocular hyperaemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
Female	3/ 99 (3%)	6/104 (6%)	0.5104 (0.1241, 2.0994) /0.351	-2.7389 (-8.3499, 2.8720) /0.339	0.5253 (0.1350, 2.0430) /0.353	0.095
Male	4/209 (2%)	1/204 (<1%)	3.9610 (0.4389, 35.7437) /0.220	1.4237 (-0.6665, 3.5139) /0.182	3.9043 (0.4401, 34.6355) /0.221	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia Female	1/ 99 (1%)	3/104 (3%)	0.3435 (0.0351, 3.3592) /0.358	-1.8745 (-5.6464, 1.8974) /0.330	0.3502 (0.0370, 3.3103) /0.360	0.142
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.317
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphadenopathy						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Deficiency anaemia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Leukocytosis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Microcytic anaemia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
Female	8/ 99 (8%)	2/104 (2%)	4.4835 (0.9281, 21.6598) /0.062	6.1577 (0.1754, 12.1401) /0.044	4.2020 (0.9146, 19.3060) /0.065	0.245
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Benign prostatic hyperplasia						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Dysmenorrhoea						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	>0.999
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menorrhagia						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Balanoposthitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cyst Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Breast pain Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysfunctional uterine bleeding						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Menometrorrhagia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menstrual disorder						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Metrorrhagia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Scrotal mass						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal discharge						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Vaginal haemorrhage						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
Female	2/ 99 (2%)	2/104 (2%)	1.0515 (0.1452, 7.6129) /0.960	0.0971 (-3.7300, 3.9243) /0.960	1.0505 (0.1509, 7.3142) /0.960	0.350
Male	7/209 (3%)	2/204 (<1%)	3.5000 (0.7184, 17.0523) /0.121	2.3689 (-0.4200, 5.1578) /0.096	3.4163 (0.7182, 16.2506) /0.123	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.513
Male	4/209 (2%)	1/204 (<1%)	3.9610 (0.4389, 35.7437) /0.220	1.4237 (-0.6665, 3.5139) /0.182	3.9043 (0.4401, 34.6355) /0.221	
Hot flush Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertensive crisis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Orthostatic hypotension						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Phlebitis						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Varicophlebitis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Varicose vein						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Venous thrombosis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
Female	3/ 99 (3%)	1/104 (<1%)	3.2187 (0.3292, 31.4746) /0.315	2.0688 (-1.7938, 5.9313) /0.294	3.1515 (0.3334, 29.7926) /0.317	0.856
Male	5/209 (2%)	2/204 (<1%)	2.4755 (0.4748, 12.9069) /0.282	1.4120 (-1.0619, 3.8858) /0.263	2.4402 (0.4789, 12.4350) /0.283	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.327
Male	3/209 (1%)	2/204 (<1%)	1.4709 (0.2432, 8.8955) /0.674	0.4550 (-1.6494, 2.5594) /0.672	1.4641 (0.2472, 8.6713) /0.674	
Pollakiuria Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.317
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Micturition urgency						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Renal impairment						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	7/209 (3%)	2/204 (<1%)	3.5000 (0.7184, 17.0523) /0.121	2.3689 (-0.4200, 5.1578) /0.096	3.4163 (0.7182, 16.2506) /0.123	
Tinnitus						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Deafness Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear discomfort						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Ear pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Excessive cerumen production						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vertigo positional						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.226
Male	4/209 (2%)	3/204 (1%)	1.3073 (0.2889, 5.9151) /0.728	0.4433 (-2.0425, 2.9290) /0.727	1.3014 (0.2949, 5.7427) /0.728	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.198
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Lipoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fibrous histiocytoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Knuckle pads						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Melanocytic naevus						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	4/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bradycardia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cardiovascular disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Palpitations						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Sinus tachycardia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ventricular extrasystoles						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.264
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	
Allergy to animal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycotic allergy						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.294
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hypogonadism						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidism						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Thyroid mass						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Social circumstances						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menopause Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Stress at work Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Biliary tract disorder						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion missed						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Dental implantation						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	50/ 99 (51%)	27/104 (26%)	2.9101 (1.6141, 5.2465) /<.001	24.5435 (11.5822, 37.5048) /<.001	1.9454 (1.3322, 2.8408) /<.001	0.988
Male	108/209 (52%)	54/204 (26%)	2.9703 (1.9659, 4.4880) /<.001	25.2041 (16.1183, 34.2898) /<.001	1.9522 (1.4998, 2.5410) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
Female	17/ 99 (17%)	15/104 (14%)	1.2301 (0.5774, 2.6207) /0.592	2.7486 (-7.2903, 12.7876) /0.592	1.1906 (0.6294, 2.2521) /0.592	0.917
Male	41/209 (20%)	35/204 (17%)	1.1784 (0.7154, 1.9410) /0.519	2.4604 (-5.0061, 9.9268) /0.518	1.1434 (0.7605, 1.7190) /0.519	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.310
Male	10/209 (5%)	3/204 (1%)	3.3668 (0.9130, 12.4159) /0.068	3.3141 (-0.0179, 6.6461) /0.051	3.2536 (0.9085, 11.6518) /0.070	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
Female	2/ 99 (2%)	2/104 (2%)	1.0515 (0.1452, 7.6129) /0.960	0.0971 (-3.7300, 3.9243) /0.960	1.0505 (0.1509, 7.3142) /0.960	0.049
Male	5/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza Female	1/ 99 (1%)	2/104 (2%)	0.5204 (0.0464, 5.8315) /0.596	-0.9130 (-4.2064, 2.3804) /0.587	0.5253 (0.0484, 5.7016) /0.597	0.196
Male	0/209	3/204 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Respiratory tract infection Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
Female	0/ 99	3/104 (3%)	<0.0001 (<0.0001, -) />0.999	-5.1377 (-25.6021, 15.3266) /0.623	<0.0001 (<0.0001, -) />0.999	0.015
Male	4/209 (2%)	1/204 (<1%)	3.9610 (0.4389, 35.7437) /0.220	1.4237 (-0.6665, 3.5139) /0.182	3.9043 (0.4401, 34.6355) /0.221	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	0.312
Male	2/209 (<1%)	4/204 (2%)	0.4831 (0.0875, 2.6669) /0.404	-1.0038 (-3.3194, 1.3117) /0.396	0.4880 (0.0904, 2.6354) /0.404	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.317
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Pharyngitis						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.966
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Conjunctivitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Oral herpes						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.031
Male	0/209	3/204 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Syphilis Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chlamydial infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.570
Male	3/209 (1%)	1/204 (<1%)	2.9563 (0.3050, 28.6570) /0.350	0.9452 (-0.9307, 2.8211) /0.323	2.9282 (0.3071, 27.9197) /0.350	
Rhinitis						
Female	1/ 99 (1%)	2/104 (2%)	0.5204 (0.0464, 5.8315) /0.596	-0.9130 (-4.2064, 2.3804) /0.587	0.5253 (0.0484, 5.7016) /0.597	0.396
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Acute sinusitis						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	>0.999
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hordeolum						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea versicolour						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Candida infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Fungal skin infection						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.179
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	
Herpes zoster						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.461
Male	4/209 (2%)	1/204 (<1%)	3.9610 (0.4389, 35.7437) /0.220	1.4237 (-0.6665, 3.5139) /0.182	3.9043 (0.4401, 34.6355) /0.221	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Onychomycosis						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Proctitis gonococcal Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth infection						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tracheitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal chlamydia infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Cystitis						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Injection site cellulitis						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal gonococcal infection						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Otitis media acute						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia Female	0/ 99	2/104 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1992 (-24.6656, 16.2672) /0.688	<0.0001 (<0.0001, -) />0.999	0.198
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Secondary syphilis Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Subcutaneous abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Urethritis gonococcal						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal infection						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	>0.999
Male	0/209	0/204	NC	NC	NC	
Orchitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Anal abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervicitis human papilloma virus						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Folliculitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Groin abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hepatitis A						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infected bite						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Liver abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Localised infection						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Oral candidiasis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Periodontitis Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Pertussis Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis chlamydial						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Proctitis herpes						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotavirus infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Tinea infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
Female	32/ 99 (32%)	3/104 (3%)	16.0796 (4.7326, 54.6321) /<.001	29.4386 (19.6801, 39.1972) /<.001	11.2053 (3.5445, 35.4237) /<.001	NC
Male	74/209 (35%)	2/204 (<1%)	55.3630 (13.3645, 229.3428) /<.001	34.4263 (27.8033, 41.0493) /<.001	36.1148 (8.9845, 145.1694) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
Female	26/ 99 (26%)	0/104	>999 (>999, >999) /NC	27.4183 (6.2364, 48.6001) /0.011	>999 (>999, >999) /NC	NC
Male	65/209 (31%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site nodule						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.294
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Pyrexia Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	3/209 (1%)	1/204 (<1%)	2.9563 (0.3050, 28.6570) /0.350	0.9452 (-0.9307, 2.8211) /0.323	2.9282 (0.3071, 27.9197) /0.350	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
Female	4/ 99 (4%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	5/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
Female	4/ 99 (4%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site erythema						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Influenza like illness						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site bruising						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Chills						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site reaction						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Discomfort Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Oedema peripheral Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Peripheral swelling						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vessel puncture site pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	2/ 99 (2%)	3/104 (3%)	0.6942 (0.1135, 4.2448) /0.693	-0.8644 (-5.1104, 3.3815) /0.690	0.7003 (0.1195, 4.1030) /0.693	0.350
Male	21/209 (10%)	12/204 (6%)	1.7872 (0.8551, 3.7355) /0.123	4.1655 (-1.0343, 9.3653) /0.116	1.7081 (0.8632, 3.3802) /0.124	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.449
Male	6/209 (3%)	2/204 (<1%)	2.9852 (0.5954, 14.9661) /0.184	1.8904 (-0.7465, 4.5273) /0.160	2.9282 (0.5980, 14.3397) /0.185	
Nausea Female	0/ 99	2/104 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1992 (-24.6656, 16.2672) /0.688	<0.0001 (<0.0001, -) />0.999	0.099
Male	3/209 (1%)	2/204 (<1%)	1.4709 (0.2432, 8.8955) /0.674	0.4550 (-1.6494, 2.5594) /0.672	1.4641 (0.2472, 8.6713) /0.674	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	
Dyspepsia Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Haemorrhoids						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	3/204 (1%)	0.3221 (0.0332, 3.1224) /0.328	-0.9921 (-2.8905, 0.9062) /0.306	0.3254 (0.0341, 3.1022) /0.329	
Abdominal pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Flatulence						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastritis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Enteritis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Inguinal hernia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Proctitis						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	3/204 (1%)	0.3221 (0.0332, 3.1224) /0.328	-0.9921 (-2.8905, 0.9062) /0.306	0.3254 (0.0341, 3.1022) /0.329	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental caries						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Abdominal hernia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Eosinophilic oesophagitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Functional gastrointestinal disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Irritable bowel syndrome						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Pancreatitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis chronic						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Proctitis ulcerative						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
Female	5/ 99 (5%)	8/104 (8%)	0.6383 (0.2015, 2.0219) /0.445	-2.6418 (-9.3377, 4.0541) /0.439	0.6566 (0.2223, 1.9390) /0.446	0.077
Male	16/209 (8%)	7/204 (3%)	2.3331 (0.9390, 5.7967) /0.068	4.2241 (-0.1615, 8.6097) /0.059	2.2310 (0.9375, 5.3092) /0.070	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.502
Male	8/209 (4%)	1/204 (<1%)	8.0796 (1.0014, 65.1913) /0.050	3.3376 (0.5654, 6.1097) /0.018	7.8086 (0.9854, 61.8748) /0.052	
Arthralgia Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.053
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.081
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal pain						
Female	1/ 99 (1%)	2/104 (2%)	0.5204 (0.0464, 5.8315) /0.596	-0.9130 (-4.2064, 2.3804) /0.587	0.5253 (0.0484, 5.7016) /0.597	0.966
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	
Muscle spasms						
Female	0/ 99	2/104 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1992 (-24.6656, 16.2672) /0.688	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Neck pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Musculoskeletal chest pain						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Arthropathy						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intervertebral disc disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Joint effusion						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Myositis Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Osteonecrosis Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Polyarthriti						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Spinal osteoarthriti						
s						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
Female	8/ 99 (8%)	5/104 (5%)	1.7407 (0.5495, 5.5140) /0.346	3.2731 (-3.4890, 10.0352) /0.343	1.6808 (0.5691, 4.9640) /0.347	0.657
Male	6/209 (3%)	5/204 (2%)	1.1764 (0.3533, 3.9166) /0.791	0.4198 (-2.6830, 3.5226) /0.791	1.1713 (0.3632, 3.7778) /0.791	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache Female	3/ 99 (3%)	1/104 (<1%)	3.2187 (0.3292, 31.4746) /0.315	2.0688 (-1.7938, 5.9313) /0.294	3.1515 (0.3334, 29.7926) /0.317	0.265
Male	3/209 (1%)	4/204 (2%)	0.7282 (0.1609, 3.2946) /0.680	-0.5254 (-3.0194, 1.9687) /0.680	0.7321 (0.1659, 3.2303) /0.680	
Dizziness Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Migraine Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervicobrachial syndrome						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Syncope						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.053
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Burning sensation						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Cerebrovascular accident						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysgeusia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Intercostal neuralgia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contractions involuntary						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Neuromuscular blockade						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post-traumatic headache						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	4/ 99 (4%)	5/104 (5%)	0.8337 (0.2173, 3.1985) /0.791	-0.7673 (-6.4196, 4.8850) /0.790	0.8404 (0.2323, 3.0398) /0.791	0.273
Male	2/209 (<1%)	7/204 (3%)	0.2719 (0.0558, 1.3248) /0.107	-2.4744 (-5.2996, 0.3508) /0.086	0.2789 (0.0586, 1.3266) /0.109	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
Female	1/ 99 (1%)	2/104 (2%)	0.5204 (0.0464, 5.8315) /0.596	-0.9130 (-4.2064, 2.3804) /0.587	0.5253 (0.0484, 5.7016) /0.597	0.738
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Oropharyngeal pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Respiratory disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Productive cough Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract congestion						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Lower respiratory tract congestion						
Female	1/ 99 (1%)	2/104 (2%)	0.5204 (0.0464, 5.8315) /0.596	-0.9130 (-4.2064, 2.3804) /0.587	0.5253 (0.0484, 5.7016) /0.597	>0.999
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Bronchospasm Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lung disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Nasal septum deviation						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Respiratory distress						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wheezing Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
Female	3/ 99 (3%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.084
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Pruritus						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Urticaria Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Decubitus ulcer						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Intertrigo						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash erythematous						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Rash maculo-papular						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	3/ 99 (3%)	1/104 (<1%)	3.2187 (0.3292, 31.4746) /0.315	2.0688 (-1.7938, 5.9313) /0.294	3.1515 (0.3334, 29.7926) /0.317	0.646
Male	15/209 (7%)	8/204 (4%)	1.8943 (0.7852, 4.5703) /0.155	3.2555 (-1.1422, 7.6532) /0.147	1.8301 (0.7932, 4.2228) /0.157	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament sprain						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Muscle strain						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	>0.999
Male	0/209	0/204	NC	NC	NC	
Arthropod bite Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epicondylitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Exposure to communicable disease						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Procedural pain						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Injection related reaction						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radius fracture						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Road traffic accident						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Upper limb fracture						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Facial bones fracture						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Foot fracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Humerus fracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injury corneal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint dislocation						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Ligament rupture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Meniscus injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skin injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tendon rupture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Tooth fracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
Female	3/ 99 (3%)	3/104 (3%)	1.0521 (0.2073, 5.3403) /0.951	0.1457 (-4.5180, 4.8093) /0.951	1.0505 (0.2171, 5.0821) /0.951	0.597
Male	9/209 (4%)	5/204 (2%)	1.7910 (0.5898, 5.4383) /0.304	1.8552 (-1.6199, 5.3303) /0.295	1.7569 (0.5990, 5.1533) /0.305	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anxiety Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.179
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Depressed mood						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression Female	1/ 99 (1%)	3/104 (3%)	0.3435 (0.0351, 3.3592) /0.358	-1.8745 (-5.6464, 1.8974) /0.330	0.3502 (0.0370, 3.3103) /0.360	0.054
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Drug abuse Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Adjustment disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depression suicidal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Drug dependence						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Suicidal behaviour						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Suicide attempt						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
Female	2/ 99 (2%)	5/104 (5%)	0.4082 (0.0773, 2.1548) /0.291	-2.7875 (-7.7458, 2.1708) /0.271	0.4202 (0.0834, 2.1160) /0.293	0.512
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	>0.999
Male	0/209	0/204	NC	NC	NC	
Hypercholesterolaemia						
Female	0/ 99	2/104 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1992 (-24.6656, 16.2672) /0.688	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

07NOV2019 02:01

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decreased appetite						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Dehydration						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetes mellitus Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Diabetic ketoacidosis Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypokalaemia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Hypophosphataemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B6 deficiency						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	3/ 99 (3%)	1/104 (<1%)	3.2187 (0.3292, 31.4746) /0.315	2.0688 (-1.7938, 5.9313) /0.294	3.1515 (0.3334, 29.7926) /0.317	0.335
Male	6/209 (3%)	6/204 (3%)	0.9754 (0.3093, 3.0755) /0.966	-0.0704 (-3.3108, 3.1701) /0.966	0.9761 (0.3201, 2.9767) /0.966	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Alanine aminotransferase increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Blood creatine phosphokinase increased						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.264
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aspartate aminotransferase increased						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Electrocardiogram QT prolonged						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Vitamin D decreased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood glucose increased						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
ECG signs of ventricular hypertrophy						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neisseria test positive						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Eye disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lacrimation increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Vitreous haematoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
Female	2/ 99 (2%)	2/104 (2%)	1.0515 (0.1452, 7.6129) /0.960	0.0971 (-3.7300, 3.9243) /0.960	1.0505 (0.1509, 7.3142) /0.960	0.264
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	>0.999
Male	0/209	0/204	NC	NC	NC	
Anaemia folate deficiency Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thrombocytopenia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
Female	3/ 99 (3%)	1/104 (<1%)	3.2187 (0.3292, 31.4746) /0.315	2.0688 (-1.7938, 5.9313) /0.294	3.1515 (0.3334, 29.7926) /0.317	0.429
Male	2/209 (<1%)	2/204 (<1%)	0.9758 (0.1362, 6.9942) /0.981	-0.0235 (-1.9129, 1.8660) /0.981	0.9761 (0.1388, 6.8636) /0.981	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign prostatic hyperplasia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Menorrhagia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Balanoposthitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Cervical dysplasia						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenomyosis Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Breast mass Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital erythema						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
Female	2/ 99 (2%)	2/104 (2%)	1.0515 (0.1452, 7.6129) /0.960	0.0971 (-3.7300, 3.9243) /0.960	1.0505 (0.1509, 7.3142) /0.960	0.690
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	0.966
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Deep vein thrombosis Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	3/209 (1%)	3/204 (1%)	0.9757 (0.1946, 4.8914) /0.976	-0.0352 (-2.3436, 2.2733) /0.976	0.9761 (0.1993, 4.7799) /0.976	
Proteinuria						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal impairment						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Renal colic						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral discharge						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	4/209 (2%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Basal cell carcinoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin papilloma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Squamous cell carcinoma of skin						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Allergy to animal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug hypersensitivity						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Endocrine disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypothyroidis						
m						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cholecystitis acute						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion spontaneous						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	6/ 99 (6%)	6/104 (6%)	1.0538 (0.3282, 3.3837) /0.930	0.2914 (-6.2026, 6.7854) /0.930	1.0505 (0.3505, 3.1484) /0.930	0.535
Male	21/209 (10%)	13/204 (6%)	1.6412 (0.7985, 3.3730) /0.178	3.6753 (-1.6018, 8.9524) /0.172	1.5767 (0.8115, 3.0636) /0.179	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.081
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Anal abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class
 and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Appendicitis Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	10/209 (5%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	9/209 (4%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pyrexia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.738
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Diarrhoea						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vomiting						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Colitis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis acute						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Rhabdomyolysis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.053
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Seizure Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Animal bite						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Skull fracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Anxiety						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Suicidal ideation Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypertriglyceridaemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	0/ 99	3/104 (3%)	<0.0001 (<0.0001, -) />0.999	-5.1377 (-25.6021, 15.3266) /0.623	<0.0001 (<0.0001, -) />0.999	0.010
Male	7/209 (3%)	2/204 (<1%)	3.5000 (0.7184, 17.0523) /0.121	2.3689 (-0.4200, 5.1578) /0.096	3.4163 (0.7182, 16.2506) /0.123	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Lipase increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood cholesterol increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Blood triglycerides increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Blood glucose increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood phosphorus decreased						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Blood creatinine increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood triglycerides						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Liver function test abnormal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst ruptured						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic kidney disease						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.047
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Papillary thyroid cancer						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seminoma Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.340
Male	7/209 (3%)	4/204 (2%)	1.7327 (0.4994, 6.0110) /0.386	1.3885 (-1.7050, 4.4820) /0.379	1.7081 (0.5077, 5.7467) /0.387	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	3/209 (1%)	1/204 (<1%)	2.9563 (0.3050, 28.6570) /0.350	0.9452 (-0.9307, 2.8211) /0.323	2.9282 (0.3071, 27.9197) /0.350	
Hepatitis A						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Acute hepatitis C						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis acute						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.513
Male	4/209 (2%)	1/204 (<1%)	3.9610 (0.4389, 35.7437) /0.220	1.4237 (-0.6665, 3.5139) /0.182	3.9043 (0.4401, 34.6355) /0.221	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.294
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Blood bilirubin increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Neutropenia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Squamous cell carcinoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hepatobiliary disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hyperbilirubinaemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 5

System Organ Class	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 5

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS

Maximum Toxicity Grade= 5

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	69/214 (32%)	79/207 (38%)	0.7710 (0.5163, 1.1514) /0.204	-5.9213 (-15.0323, 3.1898) /0.203	0.8448 (0.6512, 1.0961) /0.204	0.605
Non-White	32/ 94 (34%)	36/101 (36%)	0.9319 (0.5167, 1.6807) /0.815	-1.6010 (-14.9803, 11.7783) /0.815	0.9551 (0.6502, 1.4029) /0.815	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	93/214 (43%)	74/207 (36%)	1.3814 (0.9332, 2.0449) /0.106	7.7092 (-1.6040, 17.0223) /0.105	1.2156 (0.9580, 1.5425) /0.108	0.240
Non-White	32/ 94 (34%)	37/101 (37%)	0.8928 (0.4958, 1.6075) /0.705	-2.5911 (-16.0094, 10.8272) /0.705	0.9293 (0.6350, 1.3599) /0.706	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
White	32/214 (15%)	29/207 (14%)	1.0792 (0.6268, 1.8581) /0.783	0.9436 (-5.7784, 7.6656) /0.783	1.0674 (0.6706, 1.6988) /0.783	0.671
Non-White	8/ 94 (9%)	10/101 (10%)	0.8465 (0.3192, 2.2449) /0.738	-1.3904 (-9.4989, 6.7182) /0.737	0.8596 (0.3543, 2.0853) /0.738	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
White	15/214 (7%)	12/207 (6%)	1.2249 (0.5590, 2.6837) /0.612	1.2122 (-3.4605, 5.8850) /0.611	1.2091 (0.5800, 2.5207) /0.612	0.702
Non-White	10/ 94 (11%)	11/101 (11%)	0.9740 (0.3934, 2.4114) /0.955	-0.2528 (-8.9569, 8.4513) /0.955	0.9768 (0.4350, 2.1935) /0.955	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza						
White	12/214 (6%)	6/207 (3%)	1.9901 (0.7327, 5.4056) /0.177	2.7089 (-1.1283, 6.5462) /0.166	1.9346 (0.7399, 5.0585) /0.178	0.738
Non-White	4/ 94 (4%)	3/101 (3%)	1.4519 (0.3163, 6.6651) /0.632	1.2850 (-3.9697, 6.5397) /0.632	1.4326 (0.3293, 6.2330) /0.632	
Respiratory tract infection						
White	8/214 (4%)	9/207 (4%)	0.8544 (0.3232, 2.2586) /0.751	-0.6095 (-4.3748, 3.1558) /0.751	0.8598 (0.3382, 2.1858) /0.751	0.839
Non-White	2/ 94 (2%)	2/101 (2%)	1.0761 (0.1485, 7.7970) /0.942	0.1475 (-3.8391, 4.1340) /0.942	1.0745 (0.1544, 7.4749) /0.942	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
White	7/214 (3%)	10/207 (5%)	0.6662 (0.2487, 1.7846) /0.419	-1.5599 (-5.3297, 2.2099) /0.417	0.6771 (0.2627, 1.7452) /0.420	0.102
Non-White	0/ 94	3/101 (3%)	<0.0001 (<0.0001, -) />0.999	-5.2206 (-26.2068, 15.7655) /0.626	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Bronchitis						
White	8/214 (4%)	6/207 (3%)	1.3010 (0.4435, 3.8164) /0.632	0.8398 (-2.5783, 4.2578) /0.630	1.2897 (0.4554, 3.6530) /0.632	0.903
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Urinary tract infection						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.030
Non-White	10/ 94 (11%)	4/101 (4%)	2.8869 (0.8732, 9.5443) /0.082	6.6779 (-0.6239, 13.9797) /0.073	2.6862 (0.8721, 8.2739) /0.085	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis						
White	4/214 (2%)	6/207 (3%)	0.6381 (0.1774, 2.2947) /0.491	-1.0294 (-3.9476, 1.8888) /0.489	0.6449 (0.1846, 2.2522) /0.492	0.646
Non-White	1/ 94 (1%)	3/101 (3%)	0.3513 (0.0359, 3.4372) /0.369	-1.9065 (-5.8133, 2.0003) /0.339	0.3582 (0.0379, 3.3834) /0.370	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis						
White	5/214 (2%)	5/207 (2%)	0.9665 (0.2756, 3.3889) /0.958	-0.0790 (-2.9894, 2.8314) /0.958	0.9673 (0.2842, 3.2921) /0.958	0.042
Non-White	0/ 94	4/101 (4%)	<0.0001 (<0.0001, -) />0.999	-6.1743 (-27.1933, 14.8447) /0.565	<0.0001 (<0.0001, -) />0.999	
Lower respiratory tract infection						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	6/ 94 (6%)	4/101 (4%)	1.6534 (0.4517, 6.0525) /0.448	2.4226 (-3.8133, 8.6585) /0.446	1.6117 (0.4694, 5.5337) /0.448	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Conjunctivitis						
White	6/214 (3%)	2/207 (<1%)	2.9567 (0.5899, 14.8199) /0.187	1.8376 (-0.7446, 4.4197) /0.163	2.9019 (0.5924, 14.2138) /0.189	0.127
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Gonorrhoea						
White	6/214 (3%)	2/207 (<1%)	2.9567 (0.5899, 14.8199) /0.187	1.8376 (-0.7446, 4.4197) /0.163	2.9019 (0.5924, 14.2138) /0.189	0.127
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes						
White	3/214 (1%)	5/207 (2%)	0.5744 (0.1355, 2.4349) /0.452	-1.0136 (-3.6319, 1.6047) /0.448	0.5804 (0.1405, 2.3976) /0.452	0.167
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Sinusitis						
White	6/214 (3%)	2/207 (<1%)	2.9567 (0.5899, 14.8199) /0.187	1.8376 (-0.7446, 4.4197) /0.163	2.9019 (0.5924, 14.2138) /0.189	0.443
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis						
White	1/214 (<1%)	6/207 (3%)	0.1573 (0.0188, 1.3179) /0.088	-2.4313 (-4.8926, 0.0300) /0.053	0.1612 (0.0196, 1.3276) /0.090	0.283
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
White	4/214 (2%)	1/207 (<1%)	3.9238 (0.4349, 35.4025) /0.223	1.3861 (-0.6596, 3.4317) /0.184	3.8692 (0.4361, 34.3292) /0.224	0.205
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	
Chlamydial infection						
White	5/214 (2%)	2/207 (<1%)	2.4522 (0.4704, 12.7824) /0.287	1.3703 (-1.0529, 3.7934) /0.268	2.4182 (0.4744, 12.3257) /0.288	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis viral						
White	5/214 (2%)	1/207 (<1%)	4.9282 (0.5708, 42.5474) /0.147	1.8534 (-0.3801, 4.0868) /0.104	4.8364 (0.5699, 41.0460) /0.149	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Tonsillitis						
White	4/214 (2%)	2/207 (<1%)	1.9524 (0.3537, 10.7758) /0.443	0.9030 (-1.3483, 3.1543) /0.432	1.9346 (0.3582, 10.4487) /0.443	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis						
White	3/214 (1%)	2/207 (<1%)	1.4573 (0.2410, 8.8119) /0.682	0.4357 (-1.6275, 2.4989) /0.679	1.4509 (0.2449, 8.5949) /0.682	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Furuncle						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.202
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute sinusitis						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Herpes simplex						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Tinea cruris						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea versicolour						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.290
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Candida infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Cellulitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic tonsillitis						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Fungal infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fungal skin infection						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Genital herpes						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes simplex						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Herpes zoster						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Impetigo						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site abscess						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychomycosis						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Otitis media						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Paronychia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Proctitis gonococcal						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pulpitis dental						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Tooth infection						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tracheitis						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Urethritis chlamydial						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Abscess						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Acarodermatitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Amoebiasis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal chlamydia infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Angular cheilitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal human papilloma virus infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Body tinea						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Clostridium difficile colitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Conjunctivitis bacterial						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Cystitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Ear infection						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Enteritis infectious						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Epididymitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastric infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Gastrointestinal infection						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal viral infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Gingival abscess						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes virus infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Infection						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infection parasitic						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Injection site cellulitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Nasal herpes						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal gonococcal infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Otitis media acute						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Pneumonia mycoplasmal						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post procedural infection						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Primary syphilis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Secondary syphilis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Sexually transmitted disease						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin candida						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Staphylococcal infection						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal skin infection						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Subcutaneous abscess						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tinea pedis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Tongue fungal infection						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tooth abscess						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Ureaplasma infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis gonococcal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Vaginal infection						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Viral tonsillitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal candidiasis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Vulvovaginitis trichomonal						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
White	99/214 (46%)	10/207 (5%)	16.9591 (8.5078, 33.8056) /<.001	41.4308 (34.1398, 48.7217) /<.001	9.5762 (5.1430, 17.8307) /<.001	0.282
Non-White	36/ 94 (38%)	7/101 (7%)	8.3350 (3.4806, 19.9598) /<.001	31.3672 (20.3625, 42.3719) /<.001	5.5258 (2.5860, 11.8079) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
White	100/214 (47%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	30/ 94 (32%)	0/101	>999 (>999, >999) /NC	32.7956 (11.0777, 54.5134) /0.003	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site module						
White	21/214 (10%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	12/ 94 (13%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Fatigue						
White	17/214 (8%)	2/207 (<1%)	8.8452 (2.0172, 38.7847) /0.004	6.9777 (3.1173, 10.8382) /<.001	8.2220 (1.9235, 35.1441) /0.004	0.057
Non-White	3/ 94 (3%)	3/101 (3%)	1.0769 (0.2119, 5.4720) /0.929	0.2212 (-4.6356, 5.0779) /0.929	1.0745 (0.2223, 5.1929) /0.929	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Pyrexia						
White	13/214 (6%)	6/207 (3%)	2.1667 (0.8076, 5.8129) /0.125	3.1762 (-0.7564, 7.1088) /0.113	2.0958 (0.8119, 5.4098) /0.126	0.980
Non-White	4/ 94 (4%)	2/101 (2%)	2.2000 (0.3935, 12.3009) /0.369	2.2751 (-2.6272, 7.1774) /0.363	2.1489 (0.4029, 11.4610) /0.370	
Injection site induration						
White	15/214 (7%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	5/ 94 (5%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
White	13/214 (6%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	3/ 94 (3%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site erythema						
White	11/214 (5%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	0.301
Non-White	4/ 94 (4%)	1/101 (<1%)	4.4444 (0.4877, 40.5035) /0.186	3.2652 (-1.2490, 7.7795) /0.156	4.2979 (0.4891, 37.7637) /0.188	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
White	5/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	3/ 94 (3%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site pruritus						
White	6/214 (3%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Asthenia						
White	6/214 (3%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Injection site warmth						
White	5/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain						
White	4/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chills						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
White	5/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Malaise						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.202
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Chest pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	
Injection site reaction						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cyst						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Feeling hot						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Discomfort						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Feeling of body temperature change						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site anaesthesia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Injection site discolouration						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discomfort						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Non-cardiac chest pain						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oedema peripheral						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	29/214 (14%)	19/207 (9%)	1.5511 (0.8402, 2.8634) /0.161	4.3727 (-1.6688, 10.4141) /0.156	1.4764 (0.8552, 2.5488) /0.162	0.477
Non-White	19/ 94 (20%)	10/101 (10%)	2.3053 (1.0108, 5.2577) /0.047	10.3118 (0.3200, 20.3036) /0.043	2.0415 (1.0013, 4.1621) /0.050	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
White	10/214 (5%)	9/207 (4%)	1.0784 (0.4291, 2.7102) /0.872	0.3251 (-3.6390, 4.2892) /0.872	1.0748 (0.4458, 2.5912) /0.872	>0.999
Non-White	4/ 94 (4%)	4/101 (4%)	1.0778 (0.2617, 4.4379) /0.917	0.2949 (-5.2833, 5.8731) /0.917	1.0745 (0.2766, 4.1744) /0.917	
Nausea						
White	6/214 (3%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.207
Non-White	4/ 94 (4%)	1/101 (<1%)	4.4444 (0.4877, 40.5035) /0.186	3.2652 (-1.2490, 7.7795) /0.156	4.2979 (0.4891, 37.7637) /0.188	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Constipation						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	2/ 94 (2%)	3/101 (3%)	0.7101 (0.1160, 4.3466) /0.711	-0.8426 (-5.2553, 3.5700) /0.708	0.7163 (0.1224, 4.1928) /0.711	
Toothache						
White	2/214 (<1%)	3/207 (1%)	0.6415 (0.1061, 3.8789) /0.629	-0.5147 (-2.5914, 1.5620) /0.627	0.6449 (0.1089, 3.8200) /0.629	0.761
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.056
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
White	3/214 (1%)	1/207 (<1%)	2.9289 (0.3022, 28.3869) /0.354	0.9188 (-0.9179, 2.7554) /0.327	2.9019 (0.3043, 27.6727) /0.354	0.458
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Haemorrhoids						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	0.259
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vomiting						
White	3/214 (1%)	1/207 (<1%)	2.9289 (0.3022, 28.3869) /0.354	0.9188 (-0.9179, 2.7554) /0.327	2.9019 (0.3043, 27.6727) /0.354	0.458
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.290
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Flatulence						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal discomfort						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.089
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Abdominal pain lower						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Aphthous ulcer						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Gastritis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Abdominal distension						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Anal pruritus						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal skin tags						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Anorectal discomfort						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic gastritis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dysphagia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Epigastric discomfort						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Gingival disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoids thrombosed						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Inguinal hernia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip dry						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Lip swelling						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Mouth ulceration						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Odynophagia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Oral pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Proctitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Steatorrhoea						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tongue ulceration						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Tooth impacted						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Umbilical hernia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
White	35/214 (16%)	18/207 (9%)	2.0531 (1.1221, 3.7564) /0.020	7.6595 (1.3912, 13.9277) /0.017	1.8808 (1.1011, 3.2127) /0.021	0.586
Non-White	12/ 94 (13%)	9/101 (9%)	1.4959 (0.5997, 3.7316) /0.388	3.8551 (-4.8846, 12.5947) /0.387	1.4326 (0.6327, 3.2441) /0.389	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
White	6/214 (3%)	8/207 (4%)	0.7175 (0.2446, 2.1049) /0.546	-1.0610 (-4.4942, 2.3722) /0.545	0.7255 (0.2561, 2.0548) /0.546	0.063
Non-White	5/ 94 (5%)	1/101 (<1%)	5.6180 (0.6441, 49.0048) /0.118	4.3290 (-0.6014, 9.2595) /0.085	5.3723 (0.6393, 45.1433) /0.122	
Arthralgia						
White	4/214 (2%)	6/207 (3%)	0.6381 (0.1774, 2.2947) /0.491	-1.0294 (-3.9476, 1.8888) /0.489	0.6449 (0.1846, 2.2522) /0.492	0.742
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
White	7/214 (3%)	1/207 (<1%)	6.9662 (0.8495, 57.1236) /0.071	2.7879 (0.2244, 5.3515) /0.033	6.7710 (0.8404, 54.5551) /0.072	0.296
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
White	2/214 (<1%)	3/207 (1%)	0.6415 (0.1061, 3.8789) /0.629	-0.5147 (-2.5914, 1.5620) /0.627	0.6449 (0.1089, 3.8200) /0.629	0.683
Non-White	1/ 94 (1%)	3/101 (3%)	0.3513 (0.0359, 3.4372) /0.369	-1.9065 (-5.8133, 2.0003) /0.339	0.3582 (0.0379, 3.3834) /0.370	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal pain						
White	3/214 (1%)	2/207 (<1%)	1.4573 (0.2410, 8.8119) /0.682	0.4357 (-1.6275, 2.4989) /0.679	1.4509 (0.2449, 8.5949) /0.682	0.056
Non-White	0/ 94	3/101 (3%)	<0.0001 (<0.0001, -) />0.999	-5.2206 (-26.2068, 15.7655) /0.626	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	0.175
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Joint swelling						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.322
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.322
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Spinal pain						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tendonitis						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Bursitis						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot deformity						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Intervertebral disc protrusion						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal chest pain						
White	0/214	0/207	NC	NC	NC	NC
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Osteoarthritis						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Osteopenia						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Arthritis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Costochondritis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Dupuytren's contracture						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exostosis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Flank pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Muscle tightness						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Musculoskeletal discomfort						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Patellofemoral pain syndrome						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Scoliosis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovial cyst						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Temporomandibular joint syndrome						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tenosynovitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
White	35/214 (16%)	18/207 (9%)	2.0531 (1.1221, 3.7564) /0.020	7.6595 (1.3912, 13.9277) /0.017	1.8808 (1.1011, 3.2127) /0.021	0.694
Non-White	13/ 94 (14%)	6/101 (6%)	2.5412 (0.9239, 6.9891) /0.071	7.8892 (-0.4746, 16.2530) /0.064	2.3280 (0.9225, 5.8748) /0.074	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Headache						
White	18/214 (8%)	10/207 (5%)	1.8092 (0.8146, 4.0180) /0.145	3.5803 (-1.1484, 8.3090) /0.138	1.7411 (0.8232, 3.6824) /0.147	0.272
Non-White	8/ 94 (9%)	2/101 (2%)	4.6047 (0.9521, 22.2704) /0.058	6.5304 (0.2693, 12.7916) /0.041	4.2979 (0.9364, 19.7259) /0.061	
Dizziness						
White	6/214 (3%)	2/207 (<1%)	2.9567 (0.5899, 14.8199) /0.187	1.8376 (-0.7446, 4.4197) /0.163	2.9019 (0.5924, 14.2138) /0.189	0.627
Non-White	3/ 94 (3%)	2/101 (2%)	1.6319 (0.2666, 9.9883) /0.596	1.2113 (-3.2618, 5.6844) /0.596	1.6117 (0.2753, 9.4338) /0.597	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.951
Non-White	2/ 94 (2%)	1/101 (<1%)	2.1739 (0.1939, 24.3767) /0.529	1.1376 (-2.3608, 4.6359) /0.524	2.1489 (0.1981, 23.3113) /0.529	
Sciatica						
White	4/214 (2%)	1/207 (<1%)	3.9238 (0.4349, 35.4025) /0.223	1.3861 (-0.6596, 3.4317) /0.184	3.8692 (0.4361, 34.3292) /0.224	0.507
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Neuralgia						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervicobrachial syndrome						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Hypoaesthesia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neuropathy peripheral						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Presyncope						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Somnolence						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Anterograde amnesia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Autonomic nervous system imbalance						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Cerebral cyst						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cognitive disorder						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Disturbance in attention						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Dysaesthesia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Dystonia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Essential tremor						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Facial paralysis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Loss of consciousness						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Memory impairment						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post herpetic neuralgia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Tension headache						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
White	18/214 (8%)	17/207 (8%)	1.0264 (0.5137, 2.0510) /0.941	0.1987 (-5.0756, 5.4729) /0.941	1.0242 (0.5429, 1.9321) /0.941	0.287
Non-White	12/ 94 (13%)	7/101 (7%)	1.9652 (0.7390, 5.2260) /0.176	5.8353 (-2.5339, 14.2045) /0.172	1.8419 (0.7573, 4.4801) /0.178	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
White	6/214 (3%)	7/207 (3%)	0.8242 (0.2723, 2.4948) /0.732	-0.5779 (-3.8878, 2.7320) /0.732	0.8291 (0.2834, 2.4258) /0.732	0.232
Non-White	8/ 94 (9%)	4/101 (4%)	2.2558 (0.6562, 7.7550) /0.197	4.5502 (-2.2532, 11.3537) /0.190	2.1489 (0.6690, 6.9024) /0.199	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
White	6/214 (3%)	7/207 (3%)	0.8242 (0.2723, 2.4948) /0.732	-0.5779 (-3.8878, 2.7320) /0.732	0.8291 (0.2834, 2.4258) /0.732	0.525
Non-White	3/ 94 (3%)	2/101 (2%)	1.6319 (0.2666, 9.9883) /0.596	1.2113 (-3.2618, 5.6844) /0.596	1.6117 (0.2753, 9.4338) /0.597	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
White	1/214 (<1%)	3/207 (1%)	0.3192 (0.0329, 3.0942) /0.324	-0.9820 (-2.8489, 0.8850) /0.303	0.3224 (0.0338, 3.0747) /0.325	0.505
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	0.259
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Respiratory disorder						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	0.175
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dysphonia						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.290
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Dyspnoea White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhinitis allergic						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Emphysema						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal obstruction						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Productive cough						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pulmonary mass						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Reflux laryngitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract congestion						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Sinus pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep apnoea syndrome						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
White	21/214 (10%)	13/207 (6%)	1.6238 (0.7905, 3.3353) /0.187	3.5329 (-1.6449, 8.7107) /0.181	1.5625 (0.8038, 3.0376) /0.188	0.976
Non-White	10/ 94 (11%)	7/101 (7%)	1.5986 (0.5824, 4.3880) /0.362	3.7076 (-4.2538, 11.6690) /0.361	1.5350 (0.6092, 3.8676) /0.363	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
White	6/214 (3%)	1/207 (<1%)	5.9423 (0.7092, 49.7917) /0.100	2.3206 (-0.0843, 4.7256) /0.059	5.8037 (0.7048, 47.7922) /0.102	0.259
Non-White	4/ 94 (4%)	3/101 (3%)	1.4519 (0.3163, 6.6651) /0.632	1.2850 (-3.9697, 6.5397) /0.632	1.4326 (0.3293, 6.2330) /0.632	
Pruritus						
White	3/214 (1%)	3/207 (1%)	0.9668 (0.1929, 4.8457) /0.967	-0.0474 (-2.3127, 2.2179) /0.967	0.9673 (0.1975, 4.7379) /0.967	0.118
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Acne						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.202
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Eczema						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.037
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash pruritic White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.958
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Alopecia White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.322
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.290
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rash generalised						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.322
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seborrhoeic dermatitis						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Ecchymosis						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Dermatitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Dermatitis acneiform						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis contact						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nail bed bleeding						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Neurodermatitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Onychoclasia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Photosensitivity reaction						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Pruritus generalised						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Purpura White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Sebaceous hyperplasia White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Seborrhoea						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Skin fissures						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin lesion						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Skin mass						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Stasis dermatitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Urticaria						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
White	15/214 (7%)	17/207 (8%)	0.8424 (0.4092, 1.7346) /0.642	-1.2032 (-6.2717, 3.8653) /0.642	0.8535 (0.4378, 1.6638) /0.642	0.301
Non-White	4/ 94 (4%)	2/101 (2%)	2.2000 (0.3935, 12.3009) /0.369	2.2751 (-2.6272, 7.1774) /0.363	2.1489 (0.4029, 11.4610) /0.370	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Ligament sprain						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.192
Non-White	3/ 94 (3%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Muscle strain						
White	0/214	3/207 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.044
Non-White	2/ 94 (2%)	1/101 (<1%)	2.1739 (0.1939, 24.3767) /0.529	1.1376 (-2.3608, 4.6359) /0.524	2.1489 (0.1981, 23.3113) /0.529	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Arthropod bite						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Bone contusion						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Epicondylitis						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Exposure to communicable disease						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Procedural pain						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Soft tissue injury						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Animal bite						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Buttock injury						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Injection related reaction						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post procedural complication						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Radius fracture						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Road traffic accident						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin abrasion						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Splinter						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
White	17/214 (8%)	9/207 (4%)	1.8985 (0.8264, 4.3611) /0.131	3.5961 (-0.9695, 8.1617) /0.123	1.8271 (0.8333, 4.0059) /0.132	0.195
Non-White	3/ 94 (3%)	5/101 (5%)	0.6330 (0.1470, 2.7250) /0.539	-1.7590 (-7.2838, 3.7658) /0.533	0.6447 (0.1584, 2.6235) /0.540	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Insomnia						
White	8/214 (4%)	2/207 (<1%)	3.9806 (0.8352, 18.9714) /0.083	2.7721 (-0.0976, 5.6419) /0.058	3.8692 (0.8314, 18.0059) /0.085	0.464
Non-White	3/ 94 (3%)	2/101 (2%)	1.6319 (0.2666, 9.9883) /0.596	1.2113 (-3.2618, 5.6844) /0.596	1.6117 (0.2753, 9.4338) /0.597	
Anxiety						
White	6/214 (3%)	3/207 (1%)	1.9615 (0.4840, 7.9488) /0.345	1.3545 (-1.3919, 4.1008) /0.334	1.9346 (0.4903, 7.6336) /0.346	0.169
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
White	3/214 (1%)	2/207 (<1%)	1.4573 (0.2410, 8.8119) /0.682	0.4357 (-1.6275, 2.4989) /0.679	1.4509 (0.2449, 8.5949) /0.682	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Sleep disorder						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	0.175
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depressed mood						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Acute stress disorder						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	
Stress						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Affect lability						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Drug abuse						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritability						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Mood altered						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mood swings						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Panic disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Thinking abnormal						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
White	5/214 (2%)	6/207 (3%)	0.8014 (0.2408, 2.6675) /0.718	-0.5621 (-3.6148, 2.4906) /0.718	0.8061 (0.2498, 2.6006) /0.718	0.318
Non-White	4/ 94 (4%)	12/101 (12%)	0.3296 (0.1024, 1.0609) /0.063	-7.6259 (-15.1405, -0.1112) /0.047	0.3582 (0.1197, 1.0718) /0.066	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
White	3/214 (1%)	4/207 (2%)	0.7216 (0.1595, 3.2640) /0.672	-0.5305 (-2.9796, 1.9186) /0.671	0.7255 (0.1644, 3.2020) /0.672	0.864
Non-White	4/ 94 (4%)	7/101 (7%)	0.5968 (0.1690, 2.1083) /0.423	-2.6754 (-9.0928, 3.7421) /0.414	0.6140 (0.1857, 2.0302) /0.424	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Gout						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
<hr/>						
Hypercholesterolaemia						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperglycaemia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Increased appetite						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Decreased appetite						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Impaired fasting glucose						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Type 2 diabetes mellitus						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Vitamin B12 deficiency						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	11/214 (5%)	9/207 (4%)	1.1921 (0.4835, 2.9393) /0.703	0.7924 (-3.2660, 4.8507) /0.702	1.1822 (0.5003, 2.7937) /0.703	0.240
Non-White	4/ 94 (4%)	1/101 (<1%)	4.4444 (0.4877, 40.5035) /0.186	3.2652 (-1.2490, 7.7795) /0.156	4.2979 (0.4891, 37.7637) /0.188	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood pressure increased						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	0.078
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Alanine aminotransferase increased						
White	3/214 (1%)	1/207 (<1%)	2.9289 (0.3022, 28.3869) /0.354	0.9188 (-0.9179, 2.7554) /0.327	2.9019 (0.3043, 27.6727) /0.354	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatine phosphokinase increased						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Body temperature increased						
White	4/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine decreased						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Creatinine renal clearance decreased						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Aspartate aminotransferase increased						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Electrocardiogram QT prolonged						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Lipase increased						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Low density lipoprotein increased						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Activated partial thromboplastin time prolonged						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood cholesterol increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Blood triglycerides increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glycosylated haemoglobin increased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatic enzyme increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lipids increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Pancreatic enzymes increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Thyroxine free decreased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vitamin D decreased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Weight increased						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
White	5/214 (2%)	5/207 (2%)	0.9665 (0.2756, 3.3889) /0.958	-0.0790 (-2.9894, 2.8314) /0.958	0.9673 (0.2842, 3.2921) /0.958	0.783
Non-White	2/ 94 (2%)	3/101 (3%)	0.7101 (0.1160, 4.3466) /0.711	-0.8426 (-5.2553, 3.5700) /0.708	0.7163 (0.1224, 4.1928) /0.711	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis allergic						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Eye pruritus						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.089
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid oedema						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Vision blurred						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Cataract						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cataract subcapsular						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Conjunctival haemorrhage						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry eye						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Eye pain						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye swelling						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Ocular hyperaemia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood and lymphatic system disorders						
Any Event						
White	6/214 (3%)	2/207 (<1%)	2.9567 (0.5899, 14.8199) /0.187	1.8376 (-0.7446, 4.4197) /0.163	2.9019 (0.5924, 14.2138) /0.189	0.030
Non-White	1/ 94 (1%)	5/101 (5%)	0.2065 (0.0237, 1.8007) /0.153	-3.8867 (-8.5981, 0.8248) /0.106	0.2149 (0.0256, 1.8057) /0.157	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Anaemia						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	3/101 (3%)	<0.0001 (<0.0001, -) />0.999	-5.2206 (-26.2068, 15.7655) /0.626	<0.0001 (<0.0001, -) />0.999	
<hr/>						
Iron deficiency anaemia						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Lymphadenopathy						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Deficiency anaemia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Eosinophilia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Leukocytosis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Microcytic anaemia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
White	6/214 (3%)	4/207 (2%)	1.4639 (0.4071, 5.2644) /0.559	0.8714 (-2.0284, 3.7711) /0.556	1.4509 (0.4154, 5.0675) /0.560	0.058
Non-White	4/ 94 (4%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Benign prostatic hyperplasia						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Dysmenorrhoea						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Menorrhagia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Balanoposthitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cyst						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Breast pain						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysfunctional uterine bleeding						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Menometrorrhagia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menstrual disorder						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Metrorrhagia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Scrotal mass						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal discharge						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vaginal haemorrhage						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
White	5/214 (2%)	4/207 (2%)	1.2141 (0.3215, 4.5855) /0.775	0.4041 (-2.3551, 3.1632) /0.774	1.2091 (0.3292, 4.4403) /0.775	0.046
Non-White	4/ 94 (4%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypertension						
White	4/214 (2%)	1/207 (<1%)	3.9238 (0.4349, 35.4025) /0.223	1.3861 (-0.6596, 3.4317) /0.184	3.8692 (0.4361, 34.3292) /0.224	0.507
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hot flush						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertensive crisis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Orthostatic hypotension						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Phlebitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Varicophlebitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicose vein						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Venous thrombosis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
White	3/214 (1%)	2/207 (<1%)	1.4573 (0.2410, 8.8119) /0.682	0.4357 (-1.6275, 2.4989) /0.679	1.4509 (0.2449, 8.5949) /0.682	0.341
Non-White	5/ 94 (5%)	1/101 (<1%)	5.6180 (0.6441, 49.0048) /0.118	4.3290 (-0.6014, 9.2595) /0.085	5.3723 (0.6393, 45.1433) /0.122	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Dysuria						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.951
Non-White	2/ 94 (2%)	1/101 (<1%)	2.1739 (0.1939, 24.3767) /0.529	1.1376 (-2.3608, 4.6359) /0.524	2.1489 (0.1981, 23.3113) /0.529	
Pollakiuria						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.290
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Haematuria						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.089
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Micturition urgency						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Renal impairment						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
White	6/214 (3%)	2/207 (<1%)	2.9567 (0.5899, 14.8199) /0.187	1.8376 (-0.7446, 4.4197) /0.163	2.9019 (0.5924, 14.2138) /0.189	0.443
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tinnitus						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.089
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vertigo						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Deafness						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Ear discomfort						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Excessive cerumen production						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	4/214 (2%)	2/207 (<1%)	1.9524 (0.3537, 10.7758) /0.443	0.9030 (-1.3483, 3.1543) /0.432	1.9346 (0.3582, 10.4487) /0.443	0.070
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.202
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Lipoma						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fibrous histiocytoma						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Knuckle pads						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Melanocytic naevus						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Cardiac disorders						
Any Event						
White	4/214 (2%)	1/207 (<1%)	3.9238 (0.4349, 35.4025) /0.223	1.3861 (-0.6596, 3.4317) /0.184	3.8692 (0.4361, 34.3292) /0.224	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bradycardia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Cardiovascular disorder						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Palpitations						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Sinus tachycardia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ventricular extrasystoles						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
White	3/214 (1%)	1/207 (<1%)	2.9289 (0.3022, 28.3869) /0.354	0.9188 (-0.9179, 2.7554) /0.327	2.9019 (0.3043, 27.6727) /0.354	0.146
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.322
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Allergy to animal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycotic allergy						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.322
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypogonadism						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Hypothyroidism						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thyroid mass						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Social circumstances						
Any Event						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menopause						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Stress at work						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Biliary tract disorder						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Abortion missed						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental implantation						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	115/214 (54%)	60/207 (29%)	2.8460 (1.9021, 4.2582) /<.001	24.7528 (15.6520, 33.8536) /<.001	1.8540 (1.4485, 2.3730) /<.001	0.502
Non-White	43/ 94 (46%)	21/101 (21%)	3.2120 (1.7124, 6.0246) /<.001	24.9526 (12.1438, 37.7614) /<.001	2.2001 (1.4173, 3.4152) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	39/214 (18%)	37/207 (18%)	1.0239 (0.6230, 1.6829) /0.926	0.3499 (-6.9981, 7.6980) /0.926	1.0196 (0.6785, 1.5320) /0.926	0.265
Non-White	19/ 94 (20%)	13/101 (13%)	1.7149 (0.7942, 3.7029) /0.170	7.3415 (-3.0777, 17.7607) /0.167	1.5704 (0.8222, 2.9995) /0.172	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Nasopharyngitis						
White	7/214 (3%)	1/207 (<1%)	6.9662 (0.8495, 57.1236) /0.071	2.7879 (0.2244, 5.3515) /0.033	6.7710 (0.8404, 54.5551) /0.072	0.481
Non-White	5/ 94 (5%)	2/101 (2%)	2.7809 (0.5263, 14.6935) /0.228	3.3390 (-1.9491, 8.6270) /0.216	2.6862 (0.5339, 13.5137) /0.231	
Upper respiratory tract infection						
White	4/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.104
Non-White	3/ 94 (3%)	2/101 (2%)	1.6319 (0.2666, 9.9883) /0.596	1.2113 (-3.2618, 5.6844) /0.596	1.6117 (0.2753, 9.4338) /0.597	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza						
White	0/214	5/207 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.018
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Respiratory tract infection						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
White	3/214 (1%)	4/207 (2%)	0.7216 (0.1595, 3.2640) /0.672	-0.5305 (-2.9796, 1.9186) /0.671	0.7255 (0.1644, 3.2020) /0.672	0.200
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Bronchitis						
White	3/214 (1%)	3/207 (1%)	0.9668 (0.1929, 4.8457) /0.967	-0.0474 (-2.3127, 2.2179) /0.967	0.9673 (0.1975, 4.7379) /0.967	0.683
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	
Urinary tract infection						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Gastroenteritis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Pharyngitis						
White	1/214 (<1%)	3/207 (1%)	0.3192 (0.0329, 3.0942) /0.324	-0.9820 (-2.8489, 0.8850) /0.303	0.3224 (0.0338, 3.0747) /0.325	0.044
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lower respiratory tract infection						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Conjunctivitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Oral herpes						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Sinusitis						
White	1/214 (<1%)	3/207 (1%)	0.3192 (0.0329, 3.0942) /0.324	-0.9820 (-2.8489, 0.8850) /0.303	0.3224 (0.0338, 3.0747) /0.325	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Syphilis						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chlamydial infection						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tonsillitis						
White	4/214 (2%)	2/207 (<1%)	1.9524 (0.3537, 10.7758) /0.443	0.9030 (-1.3483, 3.1543) /0.432	1.9346 (0.3582, 10.4487) /0.443	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Rhinitis						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.175
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Furuncle						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Acute sinusitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Hordeolum						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea versicolour						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Candida infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Cellulitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Fungal skin infection						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Genital herpes						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.958
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Herpes zoster						
White	4/214 (2%)	1/207 (<1%)	3.9238 (0.4349, 35.4025) /0.223	1.3861 (-0.6596, 3.4317) /0.184	3.8692 (0.4361, 34.3292) /0.224	0.472
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Onychomycosis						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Proctitis gonococcal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth infection						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.089
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tracheitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal chlamydia infection						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Cystitis						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Injection site cellulitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal gonococcal infection						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Otitis media acute						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.202
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	
Secondary syphilis						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal infection						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Subcutaneous abscess						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tooth abscess						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Urethritis gonococcal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Orchitis						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Urethritis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Anal abscess						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervicitis human papilloma virus						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Folliculitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Groin abscess						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Hepatitis A						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Infected bite						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Liver abscess						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Localised infection						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Oral candidiasis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Periodontitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Pertussis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis chlamydial						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Proctitis herpes						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rotavirus infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Tinea infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
White	76/214 (36%)	2/207 (<1%)	56.4493 (13.6376, 233.6567) /<.001	34.5478 (27.9991, 41.0966) /<.001	36.7570 (9.1465, 147.7154) /<.001	NC
Non-White	30/ 94 (32%)	3/101 (3%)	15.3125 (4.4851, 52.2781) /<.001	28.9446 (18.9565, 38.9327) /<.001	10.7446 (3.3916, 34.0388) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
White	64/214 (30%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	27/ 94 (29%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site nodule						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Pyrexia White	3/214 (1%)	1/207 (<1%)	2.9289 (0.3022, 28.3869) /0.354	0.9188 (-0.9179, 2.7554) /0.327	2.9019 (0.3043, 27.6727) /0.354	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
White	7/214 (3%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site swelling						
White	5/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site erythema						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Influenza like illness						
White	5/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pain						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.290
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Injection site haematoma						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Discomfort						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oedema peripheral						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Chest discomfort						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peripheral swelling						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Vessel puncture site pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	17/214 (8%)	11/207 (5%)	1.5376 (0.7022, 3.3669) /0.282	2.6299 (-2.1098, 7.3696) /0.277	1.4949 (0.7176, 3.1143) /0.283	0.918
Non-White	6/ 94 (6%)	4/101 (4%)	1.6534 (0.4517, 6.0525) /0.448	2.4226 (-3.8133, 8.6585) /0.446	1.6117 (0.4694, 5.5337) /0.448	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Diarrhoea						
White	5/214 (2%)	1/207 (<1%)	4.9282 (0.5708, 42.5474) /0.147	1.8534 (-0.3801, 4.0868) /0.104	4.8364 (0.5699, 41.0460) /0.149	0.620
Non-White	2/ 94 (2%)	1/101 (<1%)	2.1739 (0.1939, 24.3767) /0.529	1.1376 (-2.3608, 4.6359) /0.524	2.1489 (0.1981, 23.3113) /0.529	
Nausea						
White	3/214 (1%)	4/207 (2%)	0.7216 (0.1595, 3.2640) /0.672	-0.5305 (-2.9796, 1.9186) /0.671	0.7255 (0.1644, 3.2020) /0.672	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Toothache						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.202
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Dyspepsia						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Haemorrhoids						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.175
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Abdominal pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Gastritis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Anal fissure						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Enteritis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Inguinal hernia						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Odynophagia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Proctitis						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	0.427
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Dental caries						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Abdominal hernia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eosinophilic oesophagitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Functional gastrointestinal disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Irritable bowel syndrome						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Pancreatitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis chronic						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Proctitis ulcerative						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
White	14/214 (7%)	10/207 (5%)	1.3790 (0.5983, 3.1784) /0.451	1.7111 (-2.7056, 6.1278) /0.448	1.3542 (0.6154, 2.9799) /0.451	0.880
Non-White	7/ 94 (7%)	5/101 (5%)	1.5448 (0.4729, 5.0463) /0.471	2.4963 (-4.2907, 9.2833) /0.471	1.5043 (0.4944, 4.5769) /0.472	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
White	7/214 (3%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.149
Non-White	3/ 94 (3%)	1/101 (<1%)	3.2967 (0.3369, 32.2603) /0.305	2.2014 (-1.8427, 6.2455) /0.286	3.2234 (0.3412, 30.4507) /0.307	
Arthralgia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	2/ 94 (2%)	1/101 (<1%)	2.1739 (0.1939, 24.3767) /0.529	1.1376 (-2.3608, 4.6359) /0.524	2.1489 (0.1981, 23.3113) /0.529	
Pain in extremity						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.751
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal pain						
White	1/214 (<1%)	3/207 (1%)	0.3192 (0.0329, 3.0942) /0.324	-0.9820 (-2.8489, 0.8850) /0.303	0.3224 (0.0338, 3.0747) /0.325	0.505
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Muscle spasms						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Muscle contracture						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Neck pain						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tendonitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Musculoskeletal chest pain						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Osteoarthritis						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Arthropathy						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intervertebral disc disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Joint effusion						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Myositis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Osteonecrosis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Polyarthrititis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Spinal osteoarthritis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
White	10/214 (5%)	7/207 (3%)	1.4006 (0.5228, 3.7518) /0.503	1.2913 (-2.4584, 5.0409) /0.500	1.3818 (0.5361, 3.5616) /0.503	0.968
Non-White	4/ 94 (4%)	3/101 (3%)	1.4519 (0.3163, 6.6651) /0.632	1.2850 (-3.9697, 6.5397) /0.632	1.4326 (0.3293, 6.2330) /0.632	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Headache						
White	4/214 (2%)	5/207 (2%)	0.7695 (0.2037, 2.9064) /0.699	-0.5463 (-3.3152, 2.2226) /0.699	0.7738 (0.2107, 2.8418) /0.699	0.082
Non-White	2/ 94 (2%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Dizziness						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Migraine						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervicobrachial syndrome						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Syncope						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Burning sensation						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cerebrovascular accident						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysgeusia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Intercostal neuralgia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Muscle contractions involuntary						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Neuromuscular blockade						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post-traumatic headache						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
White	4/214 (2%)	7/207 (3%)	0.5442 (0.1569, 1.8875) /0.338	-1.5125 (-4.5712, 1.5463) /0.332	0.5527 (0.1642, 1.8601) /0.338	0.806
Non-White	2/ 94 (2%)	5/101 (5%)	0.4174 (0.0790, 2.2052) /0.304	-2.8228 (-7.9616, 2.3159) /0.282	0.4298 (0.0854, 2.1622) /0.306	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.751
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal pain						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Sinus congestion						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Catarrh						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Productive cough						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Respiratory tract congestion						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract congestion						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	0.322
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Bronchospasm						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lung disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Nasal septum deviation						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Pneumonitis						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Respiratory distress						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wheezing						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
White	5/214 (2%)	1/207 (<1%)	4.9282 (0.5708, 42.5474) /0.147	1.8534 (-0.3801, 4.0868) /0.104	4.8364 (0.5699, 41.0460) /0.149	0.092
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Pruritus						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Eczema						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Urticaria						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Decubitus ulcer						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Intertrigo						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash erythematous						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Rash maculo-papular						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
White	16/214 (7%)	6/207 (3%)	2.7071 (1.0380, 7.0599) /0.042	4.5781 (0.3780, 8.7782) /0.033	2.5794 (1.0294, 6.4635) /0.043	0.201
Non-White	2/ 94 (2%)	3/101 (3%)	0.7101 (0.1160, 4.3466) /0.711	-0.8426 (-5.2553, 3.5700) /0.708	0.7163 (0.1224, 4.1928) /0.711	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Muscle strain						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Arthropod bite						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.089
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Epicondylitis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Exposure to communicable disease						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Procedural pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Injection related reaction						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radius fracture						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Road traffic accident						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Upper limb fracture						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Facial bones fracture						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Foot fracture						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Humerus fracture						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Injury corneal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint dislocation						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Ligament rupture						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Meniscus injury						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Skin injury						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon rupture						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Tooth fracture						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
White	7/214 (3%)	5/207 (2%)	1.3662 (0.4266, 4.3750) /0.599	0.8556 (-2.3152, 4.0264) /0.597	1.3542 (0.4367, 4.1990) /0.599	0.761
Non-White	5/ 94 (5%)	3/101 (3%)	1.8352 (0.4263, 7.9011) /0.415	2.3489 (-3.2675, 7.9652) /0.412	1.7908 (0.4400, 7.2876) /0.416	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Insomnia						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anxiety						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	0.175
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Depressed mood						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	0.372
Non-White	2/ 94 (2%)	1/101 (<1%)	2.1739 (0.1939, 24.3767) /0.529	1.1376 (-2.3608, 4.6359) /0.524	2.1489 (0.1981, 23.3113) /0.529	
Drug abuse						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Suicidal ideation						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Adjustment disorder						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depression suicidal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Drug dependence						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Suicidal behaviour						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Suicide attempt						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
White	2/214 (<1%)	3/207 (1%)	0.6415 (0.1061, 3.8789) /0.629	-0.5147 (-2.5914, 1.5620) /0.627	0.6449 (0.1089, 3.8200) /0.629	0.883
Non-White	2/ 94 (2%)	4/101 (4%)	0.5272 (0.0943, 2.9475) /0.466	-1.8327 (-6.6261, 2.9606) /0.454	0.5372 (0.1007, 2.8652) /0.467	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D deficiency						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Hypercholesterolaemia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	3/101 (3%)	<0.0001 (<0.0001, -) />0.999	-5.2206 (-26.2068, 15.7655) /0.626	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Decreased appetite						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Dehydration						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetes mellitus						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Diabetic ketoacidosis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypokalaemia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hypophosphataemia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B6 deficiency						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	7/214 (3%)	5/207 (2%)	1.3662 (0.4266, 4.3750) /0.599	0.8556 (-2.3152, 4.0264) /0.597	1.3542 (0.4367, 4.1990) /0.599	0.840
Non-White	2/ 94 (2%)	2/101 (2%)	1.0761 (0.1485, 7.7970) /0.942	0.1475 (-3.8391, 4.1340) /0.942	1.0745 (0.1544, 7.4749) /0.942	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.202
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Creatinine renal clearance decreased						
White	2/214 (<1%)	2/207 (<1%)	0.9670 (0.1349, 6.9294) /0.973	-0.0316 (-1.8857, 1.8225) /0.973	0.9673 (0.1375, 6.8030) /0.973	0.259
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aspartate aminotransferase increased						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Electrocardiogram QT prolonged						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Low density lipoprotein increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Blood cholesterol increased						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D decreased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Blood glucose increased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

ECG signs of ventricular hypertrophy						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Neisseria test positive						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Lacrimation increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous haematoma						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.078
Non-White	2/ 94 (2%)	1/101 (<1%)	2.1739 (0.1939, 24.3767) /0.529	1.1376 (-2.3608, 4.6359) /0.524	2.1489 (0.1981, 23.3113) /0.529	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	2/ 94 (2%)	1/101 (<1%)	2.1739 (0.1939, 24.3767) /0.529	1.1376 (-2.3608, 4.6359) /0.524	2.1489 (0.1981, 23.3113) /0.529	
Anaemia folate deficiency						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Thrombocytopeni						
a						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
White	5/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.001
Non-White	0/ 94	3/101 (3%)	<0.0001 (<0.0001, -) />0.999	-5.2206 (-26.2068, 15.7655) /0.626	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Benign prostatic hyperplasia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Menorrhagia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Balanoposthitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Cervical dysplasia						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenomyosis						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Breast mass						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital erythema						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.152
Non-White	4/ 94 (4%)	2/101 (2%)	2.2000 (0.3935, 12.3009) /0.369	2.2751 (-2.6272, 7.1774) /0.363	2.1489 (0.4029, 11.4610) /0.370	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypertension						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.095
Non-White	4/ 94 (4%)	1/101 (<1%)	4.4444 (0.4877, 40.5035) /0.186	3.2652 (-1.2490, 7.7795) /0.156	4.2979 (0.4891, 37.7637) /0.188	
Deep vein thrombosis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
White	3/214 (1%)	3/207 (1%)	0.9668 (0.1929, 4.8457) /0.967	-0.0474 (-2.3127, 2.2179) /0.967	0.9673 (0.1975, 4.7379) /0.967	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Proteinuria						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal impairment						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Renal colic						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral discharge						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Basal cell carcinoma						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin papilloma						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Squamous cell carcinoma of skin						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Allergy to animal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug hypersensitivity						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Hypothyroidism						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Cholecystitis acute						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion spontaneous						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	18/214 (8%)	7/207 (3%)	2.6239 (1.0722, 6.4215) /0.035	5.0296 (0.5695, 9.4896) /0.027	2.4873 (1.0611, 5.8303) /0.036	0.055
Non-White	9/ 94 (10%)	12/101 (12%)	0.7853 (0.3149, 1.9586) /0.604	-2.3067 (-10.9786, 6.3652) /0.602	0.8059 (0.3559, 1.8248) /0.605	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.096
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Anal abscess						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hepatitis A						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Appendicitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
White	8/214 (4%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	3/ 94 (3%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
White	7/214 (3%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	3/ 94 (3%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pyrexia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.293
Non-White	2/ 94 (2%)	2/101 (2%)	1.0761 (0.1485, 7.7970) /0.942	0.1475 (-3.8391, 4.1340) /0.942	1.0745 (0.1544, 7.4749) /0.942	
Diarrhoea						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Vomiting						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Colitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis acute						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	
Arthralgia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhabdomyolysis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Nervous system disorders						
Any Event						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Headache						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Seizure						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury, poisoning and procedural complications						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Eye injury						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Psychiatric disorders						
Any Event						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Depression						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Suicidal ideation						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Anxiety disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Hypertriglyceridaemia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	6/214 (3%)	3/207 (1%)	1.9615 (0.4840, 7.9488) /0.345	1.3545 (-1.3919, 4.1008) /0.334	1.9346 (0.4903, 7.6336) /0.346	0.346
Non-White	1/ 94 (1%)	2/101 (2%)	0.5323 (0.0475, 5.9683) /0.609	-0.9164 (-4.3345, 2.5018) /0.599	0.5372 (0.0495, 5.8278) /0.609	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatine phosphokinase increased						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Lipase increased						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood cholesterol increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Blood triglycerides increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Blood glucose increased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood phosphorus decreased						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Blood creatinine increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood triglycerides						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Liver function test abnormal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood and lymphatic system disorders						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst ruptured						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Chronic kidney disease						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Papillary thyroid cancer						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seminoma						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	7/214 (3%)	4/207 (2%)	1.7162 (0.4948, 5.9521) /0.395	1.3387 (-1.6939, 4.3712) /0.387	1.6928 (0.5030, 5.6967) /0.395	0.334
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	0.391
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatitis A						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Acute hepatitis C						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis acute						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	4/214 (2%)	1/207 (<1%)	3.9238 (0.4349, 35.4025) /0.223	1.3861 (-0.6596, 3.4317) /0.184	3.8692 (0.4361, 34.3292) /0.224	0.507
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatine phosphokinase increased						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Lipase increased						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood bilirubin increased						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Transaminases increased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Neutropenia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Squamous cell carcinoma						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Hepatobiliary disorders						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Hyperbilirubinaemia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 5

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 5

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury, poisoning and procedural complications						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS

Maximum Toxicity Grade= 5

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	31/ 93 (33%)	34/107 (32%)	1.0735 (0.5934, 1.9422) /0.815	1.5576 (-11.4662, 14.5815) /0.815	1.0490 (0.7034, 1.5644) /0.814	0.486
Europe	51/145 (35%)	60/146 (41%)	0.7777 (0.4840, 1.2495) /0.299	-5.9235 (-17.0635, 5.2165) /0.297	0.8559 (0.6377, 1.1486) /0.300	
Rest of World	19/ 70 (27%)	21/ 55 (38%)	0.6032 (0.2829, 1.2862) /0.191	-11.0390 (-27.5732, 5.4953) /0.191	0.7109 (0.4268, 1.1842) /0.190	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	33/ 93 (35%)	34/107 (32%)	1.1809 (0.6557, 2.1266) /0.580	3.7082 (-9.4216, 16.8379) /0.580	1.1167 (0.7560, 1.6495) /0.579	0.937
Europe	68/145 (47%)	59/146 (40%)	1.3022 (0.8185, 2.0719) /0.265	6.4856 (-4.8870, 17.8582) /0.264	1.1605 (0.8927, 1.5085) /0.266	
Rest of World	24/ 70 (34%)	18/ 55 (33%)	1.0725 (0.5072, 2.2678) /0.855	1.5584 (-15.0974, 18.2143) /0.854	1.0476 (0.6362, 1.7251) /0.855	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
North America	4/ 93 (4%)	8/107 (7%)	0.5562 (0.1619, 1.9103) /0.351	-3.1756 (-9.6437, 3.2926) /0.336	0.5753 (0.1790, 1.8491) /0.353	0.538
Europe	32/145 (22%)	28/146 (19%)	1.1934 (0.6756, 2.1082) /0.542	2.8909 (-6.4014, 12.1832) /0.542	1.1507 (0.7322, 1.8086) /0.543	
Rest of World	4/ 70 (6%)	3/ 55 (5%)	1.0505 (0.2251, 4.9023) /0.950	0.2597 (-7.8388, 8.3583) /0.950	1.0476 (0.2446, 4.4871) /0.950	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Upper respiratory tract infection						
North America	13/ 93 (14%)	10/107 (9%)	1.5762 (0.6565, 3.7848) /0.309	4.6327 (-4.3163, 13.5817) /0.310	1.4957 (0.6883, 3.2503) /0.309	0.510
Europe	4/145 (3%)	5/146 (3%)	0.8000 (0.2105, 3.0410) /0.743	-0.6660 (-4.6421, 3.3100) /0.743	0.8055 (0.2207, 2.9396) /0.743	
Rest of World	8/ 70 (11%)	8/ 55 (15%)	0.7581 (0.2651, 2.1679) /0.605	-3.1169 (-15.0486, 8.8148) /0.609	0.7857 (0.3150, 1.9601) /0.605	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Influenza						
North America	3/ 93 (3%)	2/107 (2%)	1.7500 (0.2860, 10.7062) /0.545	1.3566 (-3.0569, 5.7702) /0.547	1.7258 (0.2947, 10.1065) /0.545	0.654
Europe	11/145 (8%)	5/146 (3%)	2.3149 (0.7836, 6.8389) /0.129	4.1615 (-1.0610, 9.3841) /0.118	2.2152 (0.7894, 6.2163) /0.131	
Rest of World	2/ 70 (3%)	2/ 55 (4%)	0.7794 (0.1063, 5.7166) /0.806	-0.7792 (-7.0805, 5.5220) /0.808	0.7857 (0.1143, 5.4017) /0.806	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
North America	0/ 93	0/107	NC	NC	NC	0.995
Europe	9/145 (6%)	10/146 (7%)	0.9000 (0.3546, 2.2842) /0.825	-0.6424 (-6.3178, 5.0330) /0.824	0.9062 (0.3794, 2.1646) /0.825	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	0.234
Europe	7/145 (5%)	10/146 (7%)	0.6899 (0.2552, 1.8649) /0.464	-2.0217 (-7.4031, 3.3597) /0.462	0.7048 (0.2758, 1.8010) /0.465	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis						
North America	4/ 93 (4%)	2/107 (2%)	2.3595 (0.4222, 13.1863) /0.328	2.4319 (-2.4247, 7.2886) /0.326	2.3011 (0.4312, 12.2786) /0.329	0.694
Europe	4/145 (3%)	4/146 (3%)	1.0071 (0.2470, 4.1059) /0.992	0.0189 (-3.7385, 3.7763) /0.992	1.0069 (0.2567, 3.9495) /0.992	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract infection						
North America	6/ 93 (6%)	2/107 (2%)	3.6207 (0.7127, 18.3935) /0.121	4.5825 (-1.0314, 10.1963) /0.110	3.4516 (0.7138, 16.6905) /0.123	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	4/ 70 (6%)	4/ 55 (7%)	0.7727 (0.1843, 3.2396) /0.724	-1.5584 (-10.3145, 7.1976) /0.727	0.7857 (0.2057, 3.0011) /0.724	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
North America	3/ 93 (3%)	2/107 (2%)	1.7500 (0.2860, 10.7062) /0.545	1.3566 (-3.0569, 5.7702) /0.547	1.7258 (0.2947, 10.1065) /0.545	0.191
Europe	1/145 (<1%)	6/146 (4%)	0.1620 (0.0193, 1.3632) /0.094	-3.4199 (-6.9104, 0.0705) /0.055	0.1678 (0.0205, 1.3766) /0.096	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis						
North America	1/ 93 (1%)	3/107 (3%)	0.3768 (0.0385, 3.6858) /0.402	-1.7285 (-5.4938, 2.0368) /0.368	0.3835 (0.0406, 3.6243) /0.403	0.224
Europe	4/145 (3%)	4/146 (3%)	1.0071 (0.2470, 4.1059) /0.992	0.0189 (-3.7385, 3.7763) /0.992	1.0069 (0.2567, 3.9495) /0.992	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	6/ 70 (9%)	4/ 55 (7%)	1.1953 (0.3201, 4.4636) /0.791	1.2987 (-8.1938, 10.7912) /0.789	1.1786 (0.3497, 3.9716) /0.791	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	4/145 (3%)	3/146 (2%)	1.3522 (0.2973, 6.1514) /0.696	0.7038 (-2.8178, 4.2255) /0.695	1.3425 (0.3059, 5.8930) /0.696	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gonorrhoea						
North America	3/ 93 (3%)	2/107 (2%)	1.7500 (0.2860, 10.7062) /0.545	1.3566 (-3.0569, 5.7702) /0.547	1.7258 (0.2947, 10.1065) /0.545	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral herpes						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.141
Europe	2/145 (1%)	5/146 (3%)	0.3944 (0.0753, 2.0665) /0.271	-2.0453 (-5.5533, 1.4626) /0.253	0.4028 (0.0794, 2.0426) /0.272	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinusitis						
North America	2/ 93 (2%)	2/107 (2%)	1.1538 (0.1593, 8.3567) /0.887	0.2814 (-3.6272, 4.1900) /0.888	1.1505 (0.1653, 8.0076) /0.887	NC
Europe	4/145 (3%)	0/146	>999 (>999, >999) /NC	5.0157 (-11.8696, 21.9009) /0.560	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Syphilis						
North America	1/ 93 (1%)	3/107 (3%)	0.3768 (0.0385, 3.6858) /0.402	-1.7285 (-5.4938, 2.0368) /0.368	0.3835 (0.0406, 3.6243) /0.403	0.966
Europe	1/145 (<1%)	4/146 (3%)	0.2465 (0.0272, 2.2328) /0.213	-2.0501 (-5.0209, 0.9207) /0.176	0.2517 (0.0285, 2.2251) /0.215	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	0.086
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	4/ 70 (6%)	1/ 55 (2%)	3.2727 (0.3552, 30.1518) /0.295	3.8961 (-2.5873, 10.3795) /0.239	3.1429 (0.3615, 27.3248) /0.299	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydial infection						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	0.216
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis viral						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhinitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Furuncle						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute sinusitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Herpes simplex						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Tinea cruris						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea versicolour						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Candida infection						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cellulitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic tonsillitis						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fungal infection						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fungal skin infection						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes simplex						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Impetigo						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Onychomycosis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis gonococcal						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Pulpitis dental						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Tooth infection						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tracheitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	2/146 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6449 (-20.6173, 13.3275) /0.674	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis chlamydial						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	
Acarodermatitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Amoebiasis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Anal chlamydia infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Angular cheilitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal human papilloma virus infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body tinea						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Clostridium difficile colitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis bacterial						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Ear infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Enteritis infectious						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Epididymitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Gastric infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestina						
l infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal viral infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival abscess						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Herpes virus infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infection parasitic						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site cellulitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Laryngitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal herpes						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis media acute						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pneumonia mycoplasmal						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post procedural infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Primary syphilis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted disease						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin candida						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Staphylococcal infection						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal skin infection						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Tinea pedis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tongue fungal infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tooth abscess						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Ureaplasma infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis gonococcal						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal infection						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Viral infection						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral tonsillitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal candidiasis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginitis trichomonal						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
North America	36/ 93 (39%)	4/107 (4%)	16.2631 (5.5092, 48.0084) /<.001	34.9714 (24.4395, 45.5032) /<.001	10.3548 (3.8287, 28.0047) /<.001	0.580
Europe	74/145 (51%)	9/146 (6%)	15.8654 (7.5024, 33.5509) /<.001	44.8701 (35.8466, 53.8936) /<.001	8.2789 (4.3106, 15.9005) /<.001	
Rest of World	25/ 70 (36%)	4/ 55 (7%)	7.0833 (2.2904, 21.9063) /<.001	28.4416 (15.2849, 41.5982) /<.001	4.9107 (1.8163, 13.2773) /0.002	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
North America	29/ 93 (31%)	0/107	>999 (>999, >999) /NC	32.0991 (10.8760, 53.3221) /0.003	>999 (>999, >999) /NC	NC
Europe	76/145 (52%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	25/ 70 (36%)	0/ 55	>999 (>999, >999) /NC	36.4100 (7.6602, 65.1597) /0.013	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site						
module						
North America	13/ 93 (14%)	0/107	>999 (>999, >999) /NC	15.7290 (-4.7457, 36.2038) /0.132	>999 (>999, >999) /NC	NC
Europe	12/145 (8%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	8/ 70 (11%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fatigue						
North America	8/ 93 (9%)	3/107 (3%)	3.2627 (0.8395, 12.6805) /0.088	5.7984 (-0.7023, 12.2991) /0.080	3.0681 (0.8383, 11.2295) /0.090	0.705
Europe	11/145 (8%)	2/146 (1%)	5.9104 (1.2864, 27.1562) /0.022	6.2163 (1.5123, 10.9204) /0.010	5.5379 (1.2493, 24.5480) /0.024	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyrexia						
North America	3/ 93 (3%)	3/107 (3%)	1.1556 (0.2275, 5.8683) /0.862	0.4221 (-4.3401, 5.1842) /0.862	1.1505 (0.2379, 5.5635) /0.862	0.387
Europe	12/145 (8%)	5/146 (3%)	2.5444 (0.8729, 7.4165) /0.087	4.8512 (-0.5165, 10.2190) /0.077	2.4165 (0.8734, 6.6858) /0.089	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
North America	4/ 93 (4%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	13/145 (9%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	3/ 70 (4%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
North America	6/ 93 (6%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	8/145 (6%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site erythema						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	9/145 (6%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.595
Europe	3/145 (2%)	2/146 (1%)	1.5211 (0.2504, 9.2405) /0.649	0.6991 (-2.2880, 3.6862) /0.646	1.5103 (0.2561, 8.9059) /0.649	
Rest of World	2/ 70 (3%)	1/ 55 (2%)	1.5882 (0.1403, 17.9846) /0.709	1.0390 (-4.2241, 6.3020) /0.699	1.5714 (0.1463, 16.8832) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
North America	6/ 93 (6%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pruritus						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	6/145 (4%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Asthenia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	5/145 (3%)	0/146	>999 (>999, >999) /NC	5.6819 (-11.2187, 22.5824) /0.510	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	3/ 70 (4%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain						
North America	3/ 93 (3%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chills						
North America	3/ 93 (3%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	4/145 (3%)	0/146	>999 (>999, >999) /NC	5.0157 (-11.8696, 21.9009) /0.560	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest pain						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cyst						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Discomfort						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Feeling of body temperature change						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site anaesthesia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Injection site discolouration						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discomfort						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oedema peripheral						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	17/ 93 (18%)	7/107 (7%)	3.1955 (1.2616, 8.0938) /0.014	11.7375 (2.5913, 20.8838) /0.012	2.7942 (1.2121, 6.4412) /0.016	0.059
Europe	17/145 (12%)	18/146 (12%)	0.9444 (0.4659, 1.9146) /0.874	-0.6046 (-8.0785, 6.8692) /0.874	0.9510 (0.5107, 1.7709) /0.874	
Rest of World	14/ 70 (20%)	4/ 55 (7%)	3.1875 (0.9852, 10.3130) /0.053	12.7273 (1.1123, 24.3422) /0.032	2.7500 (0.9589, 7.8867) /0.060	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diarrhoea						
North America	5/ 93 (5%)	5/107 (5%)	1.1591 (0.3249, 4.1355) /0.820	0.7034 (-5.3798, 6.7867) /0.821	1.1505 (0.3438, 3.8508) /0.820	0.436
Europe	5/145 (3%)	7/146 (5%)	0.7092 (0.2198, 2.2882) /0.565	-1.3462 (-5.9103, 3.2178) /0.563	0.7192 (0.2336, 2.2140) /0.566	
Rest of World	4/ 70 (6%)	1/ 55 (2%)	3.2727 (0.3552, 30.1518) /0.295	3.8961 (-2.5873, 10.3795) /0.239	3.1429 (0.3615, 27.3248) /0.299	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nausea						
North America	5/ 93 (5%)	1/107 (<1%)	6.0227 (0.6907, 52.5150) /0.104	4.4418 (-0.4915, 9.3751) /0.078	5.7527 (0.6843, 48.3586) /0.107	0.587
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	3/ 70 (4%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Constipation						
North America	2/ 93 (2%)	2/107 (2%)	1.1538 (0.1593, 8.3567) /0.887	0.2814 (-3.6272, 4.1900) /0.888	1.1505 (0.1653, 8.0076) /0.887	0.118
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Toothache						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.950
Europe	2/145 (1%)	3/146 (2%)	0.6667 (0.1097, 4.0499) /0.660	-0.6755 (-3.6586, 2.3077) /0.657	0.6713 (0.1138, 3.9582) /0.660	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
North America	3/ 93 (3%)	1/107 (<1%)	3.5333 (0.3612, 34.5630) /0.278	2.2912 (-1.7360, 6.3185) /0.265	3.4516 (0.3652, 32.6189) /0.280	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
North America	0/ 93	0/107	NC	NC	NC	0.972
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	2/ 70 (3%)	1/ 55 (2%)	1.5882 (0.1403, 17.9846) /0.709	1.0390 (-4.2241, 6.3020) /0.699	1.5714 (0.1463, 16.8832) /0.709	
Vomiting						
North America	4/ 93 (4%)	1/107 (<1%)	4.7640 (0.5230, 43.3995) /0.166	3.3665 (-1.1419, 7.8749) /0.143	4.6022 (0.5236, 40.4530) /0.169	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Flatulence						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain lower						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain upper						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aphthous ulcer						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastritis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal distension						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Anal fissure						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal pruritus						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Anal skin tags						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal discomfort						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic gastritis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphagia						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Enteritis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epigastric discomfort						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival disorder						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoids thrombosed						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Inguinal hernia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Lip dry						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip swelling						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Mouth ulceration						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Oral disorder						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral pain						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Proctitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Steatorrhoea						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tongue ulceration						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Tooth impacted						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Umbilical hernia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
North America	15/ 93 (16%)	8/107 (7%)	2.3798 (0.9599, 5.9000) /0.061	8.6524 (-0.3316, 17.6364) /0.059	2.1573 (0.9579, 4.8582) /0.063	0.496
Europe	26/145 (18%)	14/146 (10%)	2.0600 (1.0277, 4.1292) /0.042	8.3420 (0.4809, 16.2031) /0.038	1.8700 (1.0183, 3.4337) /0.044	
Rest of World	6/ 70 (9%)	5/ 55 (9%)	0.9375 (0.2704, 3.2498) /0.919	-0.5195 (-10.5559, 9.5169) /0.919	0.9429 (0.3036, 2.9277) /0.919	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Back pain						
North America	3/ 93 (3%)	3/107 (3%)	1.1556 (0.2275, 5.8683) /0.862	0.4221 (-4.3401, 5.1842) /0.862	1.1505 (0.2379, 5.5635) /0.862	0.180
Europe	5/145 (3%)	6/146 (4%)	0.8333 (0.2486, 2.7938) /0.768	-0.6613 (-5.0418, 3.7192) /0.767	0.8391 (0.2619, 2.6883) /0.768	
Rest of World	3/ 70 (4%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthralgia						
North America	2/ 93 (2%)	2/107 (2%)	1.1538 (0.1593, 8.3567) /0.887	0.2814 (-3.6272, 4.1900) /0.888	1.1505 (0.1653, 8.0076) /0.887	0.465
Europe	3/145 (2%)	4/146 (3%)	0.7500 (0.1649, 3.4118) /0.710	-0.6708 (-4.1891, 2.8476) /0.709	0.7552 (0.1720, 3.3148) /0.710	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Myalgia						
North America	3/ 93 (3%)	1/107 (<1%)	3.5333 (0.3612, 34.5630) /0.278	2.2912 (-1.7360, 6.3185) /0.265	3.4516 (0.3652, 32.6189) /0.280	NC
Europe	5/145 (3%)	0/146	>999 (>999, >999) /NC	5.6819 (-11.2187, 22.5824) /0.510	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pain in extremity						
North America	0/ 93	4/107 (4%)	<0.0001 (<0.0001, -) />0.999	-5.9609 (-27.0319, 15.1100) /0.579	<0.0001 (<0.0001, -) />0.999	0.127
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	2/ 70 (3%)	1/ 55 (2%)	1.5882 (0.1403, 17.9846) /0.709	1.0390 (-4.2241, 6.3020) /0.699	1.5714 (0.1463, 16.8832) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal pain						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	0.186
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint swelling						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Muscle contracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Bursitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot deformity						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc protrusion						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal chest pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteopenia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	
Arthritis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Costochondritis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Dupuytren's contracture						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exostosis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Flank pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle tightness						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Patellofemoral pain syndrome						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Scoliosis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovial cyst						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temporomandibular joint syndrome						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Tenosynovitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
North America	14/ 93 (15%)	8/107 (7%)	2.1930 (0.8761, 5.4898) /0.093	7.5771 (-1.2351, 16.3894) /0.092	2.0134 (0.8841, 4.5854) /0.096	0.752
Europe	25/145 (17%)	11/146 (8%)	2.5568 (1.2071, 5.4158) /0.014	9.7071 (2.2150, 17.1993) /0.011	2.2884 (1.1700, 4.4760) /0.016	
Rest of World	9/ 70 (13%)	5/ 55 (9%)	1.4754 (0.4647, 4.6848) /0.509	3.7662 (-7.1520, 14.6845) /0.499	1.4143 (0.5026, 3.9798) /0.511	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
North America	5/ 93 (5%)	3/107 (3%)	1.9697 (0.4578, 8.4750) /0.363	2.5726 (-2.9769, 8.1221) /0.364	1.9176 (0.4709, 7.8083) /0.363	0.816
Europe	16/145 (11%)	8/146 (5%)	2.1395 (0.8857, 5.1684) /0.091	5.5550 (-0.7406, 11.8507) /0.084	2.0138 (0.8896, 4.5586) /0.093	
Rest of World	5/ 70 (7%)	1/ 55 (2%)	4.1538 (0.4709, 36.6416) /0.200	5.3247 (-1.6658, 12.3152) /0.135	3.9286 (0.4726, 32.6572) /0.205	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness						
North America	4/ 93 (4%)	1/107 (<1%)	4.7640 (0.5230, 43.3995) /0.166	3.3665 (-1.1419, 7.8749) /0.143	4.6022 (0.5236, 40.4530) /0.169	0.221
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	1/ 70 (1%)	2/ 55 (4%)	0.3841 (0.0339, 4.3494) /0.440	-2.2078 (-7.8825, 3.4669) /0.446	0.3929 (0.0366, 4.2208) /0.441	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Paraesthesia						
North America	3/ 93 (3%)	2/107 (2%)	1.7500 (0.2860, 10.7062) /0.545	1.3566 (-3.0569, 5.7702) /0.547	1.7258 (0.2947, 10.1065) /0.545	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	3/145 (2%)	1/146 (<1%)	3.0634 (0.3149, 29.7994) /0.335	1.3840 (-1.2913, 4.0594) /0.311	3.0207 (0.3179, 28.7018) /0.336	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuralgia						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Cervicobrachial syndrome						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	2/146 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6449 (-20.6173, 13.3275) /0.674	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neuropathy peripheral						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Somnolence						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anterograde amnesia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Autonomic nervous system imbalance						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cerebral cyst						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Cognitive disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Dysaesthesia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dystonia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Essential tremor						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Facial paralysis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Loss of consciousness						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Memory impairment						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post herpetic neuralgia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tension headache						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	11/ 93 (12%)	15/107 (14%)	0.8228 (0.3577, 1.8926) /0.646	-2.1907 (-11.4833, 7.1018) /0.644	0.8437 (0.4079, 1.7451) /0.647	0.291
Europe	11/145 (8%)	6/146 (4%)	1.9154 (0.6889, 5.3253) /0.213	3.4766 (-1.9031, 8.8564) /0.205	1.8460 (0.7013, 4.8589) /0.214	
Rest of World	8/ 70 (11%)	3/ 55 (5%)	2.2366 (0.5643, 8.8647) /0.252	5.9740 (-3.5951, 15.5432) /0.221	2.0952 (0.5831, 7.5286) /0.257	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cough						
North America	3/ 93 (3%)	8/107 (7%)	0.4125 (0.1062, 1.6028) /0.201	-4.2508 (-10.3933, 1.8916) /0.175	0.4315 (0.1179, 1.5791) /0.204	0.064
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	7/ 70 (10%)	2/ 55 (4%)	2.9444 (0.5866, 14.7801) /0.190	6.3636 (-2.2308, 14.9581) /0.147	2.7500 (0.5947, 12.7161) /0.195	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal pain						
North America	5/ 93 (5%)	5/107 (5%)	1.1591 (0.3249, 4.1355) /0.820	0.7034 (-5.3798, 6.7867) /0.821	1.1505 (0.3438, 3.8508) /0.820	0.947
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	2/ 70 (3%)	2/ 55 (4%)	0.7794 (0.1063, 5.7166) /0.806	-0.7792 (-7.0805, 5.5220) /0.808	0.7857 (0.1143, 5.4017) /0.806	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal congestion						
North America	1/ 93 (1%)	4/107 (4%)	0.2799 (0.0307, 2.5495) /0.259	-2.6630 (-6.8240, 1.4979) /0.210	0.2876 (0.0327, 2.5283) /0.261	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
North America	3/ 93 (3%)	2/107 (2%)	1.7500 (0.2860, 10.7062) /0.545	1.3566 (-3.0569, 5.7702) /0.547	1.7258 (0.2947, 10.1065) /0.545	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Respiratory disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea						
North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphonia						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Catarrh						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dyspnoea						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhinitis allergic						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Emphysema						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Nasal obstruction						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Productive cough						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	
Pulmonary mass						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reflux laryngitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract congestion						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sleep apnoea syndrome						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
North America	10/ 93 (11%)	8/107 (7%)	1.4910 (0.5627, 3.9503) /0.422	3.2761 (-4.7536, 11.3057) /0.424	1.4382 (0.5923, 3.4923) /0.422	0.959
Europe	12/145 (8%)	8/146 (5%)	1.5564 (0.6167, 3.9280) /0.349	2.7964 (-3.0120, 8.6048) /0.345	1.5103 (0.6362, 3.5856) /0.350	
Rest of World	9/ 70 (13%)	4/ 55 (7%)	1.8811 (0.5470, 6.4688) /0.316	5.5844 (-4.8361, 16.0050) /0.294	1.7679 (0.5747, 5.4378) /0.320	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
North America	4/ 93 (4%)	2/107 (2%)	2.3595 (0.4222, 13.1863) /0.328	2.4319 (-2.4247, 7.2886) /0.326	2.3011 (0.4312, 12.2786) /0.329	0.959
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	4/ 70 (6%)	1/ 55 (2%)	3.2727 (0.3552, 30.1518) /0.295	3.8961 (-2.5873, 10.3795) /0.239	3.1429 (0.3615, 27.3248) /0.299	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.390
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acne						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.474
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eczema						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash pruritic						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Alopecia						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermal cyst						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash generalised						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seborrhoeic dermatitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ecchymosis						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Dermatitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis acneiform						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis contact						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nail bed bleeding						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neurodermatitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Onychoclasia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Photosensitivity reaction						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Purpura						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sebacous hyperplasia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoea						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Skin fissures						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin lesion						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Skin mass						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Stasis dermatitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urticaria						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	7/ 93 (8%)	12/107 (11%)	0.6444 (0.2426, 1.7113) /0.378	-3.6881 (-11.7192, 4.3430) /0.368	0.6711 (0.2757, 1.6340) /0.380	0.225
Europe	9/145 (6%)	4/146 (3%)	2.3493 (0.7069, 7.8079) /0.163	3.4672 (-1.2693, 8.2037) /0.151	2.2655 (0.7137, 7.1919) /0.165	
Rest of World	3/ 70 (4%)	3/ 55 (5%)	0.7761 (0.1504, 4.0042) /0.762	-1.1688 (-8.8193, 6.4817) /0.765	0.7857 (0.1650, 3.7423) /0.762	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
North America	3/ 93 (3%)	1/107 (<1%)	3.5333 (0.3612, 34.5630) /0.278	2.2912 (-1.7360, 6.3185) /0.265	3.4516 (0.3652, 32.6189) /0.280	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
North America	1/ 93 (1%)	3/107 (3%)	0.3768 (0.0385, 3.6858) /0.402	-1.7285 (-5.4938, 2.0368) /0.368	0.3835 (0.0406, 3.6243) /0.403	0.251
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Contusion						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bone contusion						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Epicondylitis						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exposure to communicable disease						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Procedural pain North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Soft tissue injury						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Animal bite						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Buttock injury						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection related reaction						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post procedural complication						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radius fracture						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Rib fracture						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Road traffic accident						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Skin abrasion						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Splinter						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
North America	11/ 93 (12%)	7/107 (7%)	1.9164 (0.7109, 5.1657) /0.199	5.2859 (-2.7781, 13.3499) /0.199	1.8080 (0.7307, 4.4736) /0.200	0.295
Europe	7/145 (5%)	7/146 (5%)	1.0072 (0.3442, 2.9477) /0.989	0.0331 (-4.8845, 4.9506) /0.989	1.0069 (0.3623, 2.7983) /0.989	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Insomnia						
North America	6/ 93 (6%)	3/107 (3%)	2.3908 (0.5809, 9.8403) /0.227	3.6479 (-2.2439, 9.5397) /0.225	2.3011 (0.5919, 8.9454) /0.229	0.584
Europe	3/145 (2%)	1/146 (<1%)	3.0634 (0.3149, 29.7994) /0.335	1.3840 (-1.2913, 4.0594) /0.311	3.0207 (0.3179, 28.7018) /0.336	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anxiety						
North America	5/ 93 (5%)	1/107 (<1%)	6.0227 (0.6907, 52.5150) /0.104	4.4418 (-0.4915, 9.3751) /0.078	5.7527 (0.6843, 48.3586) /0.107	0.134
Europe	1/145 (<1%)	3/146 (2%)	0.3310 (0.0340, 3.2200) /0.341	-1.3651 (-4.0316, 1.3013) /0.316	0.3356 (0.0353, 3.1891) /0.342	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depressed mood						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute stress disorder						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depression						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Stress						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Affect lability						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Drug abuse						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritability						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Mood altered						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Mood swings						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Panic disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thinking abnormal						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
North America	2/ 93 (2%)	9/107 (8%)	0.2393 (0.0504, 1.1372) /0.072	-6.2607 (-12.2897, -0.2316) /0.042	0.2557 (0.0567, 1.1536) /0.076	0.525
Europe	3/145 (2%)	4/146 (3%)	0.7500 (0.1649, 3.4118) /0.710	-0.6708 (-4.1891, 2.8476) /0.709	0.7552 (0.1720, 3.3148) /0.710	
Rest of World	4/ 70 (6%)	5/ 55 (9%)	0.6061 (0.1547, 2.3736) /0.472	-3.3766 (-12.7195, 5.9663) /0.479	0.6286 (0.1771, 2.2304) /0.472	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D deficiency						
North America	1/ 93 (1%)	7/107 (7%)	0.1553 (0.0187, 1.2863) /0.084	-5.4668 (-10.5994, -0.3341) /0.037	0.1644 (0.0206, 1.3114) /0.088	0.082
Europe	2/145 (1%)	3/146 (2%)	0.6667 (0.1097, 4.0499) /0.660	-0.6755 (-3.6586, 2.3077) /0.657	0.6713 (0.1138, 3.9582) /0.660	
Rest of World	4/ 70 (6%)	1/ 55 (2%)	3.2727 (0.3552, 30.1518) /0.295	3.8961 (-2.5873, 10.3795) /0.239	3.1429 (0.3615, 27.3248) /0.299	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gout						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperglycaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Increased appetite						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decreased appetite						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Impaired fasting glucose						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Type 2 diabetes mellitus						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B12 deficiency						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	3/ 93 (3%)	5/107 (5%)	0.6800 (0.1581, 2.9256) /0.604	-1.4471 (-6.8218, 3.9276) /0.598	0.6903 (0.1695, 2.8110) /0.605	0.385
Europe	9/145 (6%)	4/146 (3%)	2.3493 (0.7069, 7.8079) /0.163	3.4672 (-1.2693, 8.2037) /0.151	2.2655 (0.7137, 7.1919) /0.165	
Rest of World	3/ 70 (4%)	1/ 55 (2%)	2.4179 (0.2445, 23.9097) /0.450	2.4675 (-3.4468, 8.3819) /0.414	2.3571 (0.2521, 22.0408) /0.452	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood pressure increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Alanine aminotransferase increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	3/145 (2%)	1/146 (<1%)	3.0634 (0.3149, 29.7994) /0.335	1.3840 (-1.2913, 4.0594) /0.311	3.0207 (0.3179, 28.7018) /0.336	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatine phosphokinase increased						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body temperature increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	4/145 (3%)	0/146	>999 (>999, >999) /NC	5.0157 (-11.8696, 21.9009) /0.560	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine decreased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	2/146 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6449 (-20.6173, 13.3275) /0.674	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Creatinine renal clearance decreased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aspartate aminotransferase increased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	2/146 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6449 (-20.6173, 13.3275) /0.674	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Activated partial thromboplastin time prolonged						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood triglycerides increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glycosylated haemoglobin increased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic enzyme increased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lipids increased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatic enzymes increased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thyroxine free decreased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D decreased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight increased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.815
Europe	3/145 (2%)	5/146 (3%)	0.5958 (0.1397, 2.5404) /0.484	-1.3557 (-5.1067, 2.3953) /0.479	0.6041 (0.1471, 2.4814) /0.484	
Rest of World	3/ 70 (4%)	2/ 55 (4%)	1.1866 (0.1913, 7.3609) /0.854	0.6494 (-6.2053, 7.5040) /0.853	1.1786 (0.2040, 6.8093) /0.854	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chalazion						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis allergic						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pruritus						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eyelid oedema						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vision blurred						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Cataract						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cataract subcapsular						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctival haemorrhage						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dry eye						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Eye pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye swelling						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Ocular hyperaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	0.565
Europe	4/145 (3%)	4/146 (3%)	1.0071 (0.2470, 4.1059) /0.992	0.0189 (-3.7385, 3.7763) /0.992	1.0069 (0.2567, 3.9495) /0.992	
Rest of World	1/ 70 (1%)	2/ 55 (4%)	0.3841 (0.0339, 4.3494) /0.440	-2.2078 (-7.8825, 3.4669) /0.446	0.3929 (0.0366, 4.2208) /0.441	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Iron deficiency anaemia						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Deficiency anaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Leukocytosis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Microcytic anaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
North America	3/ 93 (3%)	2/107 (2%)	1.7500 (0.2860, 10.7062) /0.545	1.3566 (-3.0569, 5.7702) /0.547	1.7258 (0.2947, 10.1065) /0.545	0.676
Europe	5/145 (3%)	1/146 (<1%)	5.1786 (0.5975, 44.8841) /0.136	2.7633 (-0.4940, 6.0207) /0.096	5.0345 (0.5955, 42.5641) /0.138	
Rest of World	2/ 70 (3%)	1/ 55 (2%)	1.5882 (0.1403, 17.9846) /0.709	1.0390 (-4.2241, 6.3020) /0.699	1.5714 (0.1463, 16.8832) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Benign prostatic hyperplasia						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysmenorrhoea						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menorrhagia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Balanoposthitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cyst						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	
Breast pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysfunctional uterine bleeding						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menometrorrhagi						
^a North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Menstrual disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metrorrhagia						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Penile pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Scrotal mass						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal discharge						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal haemorrhage						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	0.322
Europe	4/145 (3%)	3/146 (2%)	1.3522 (0.2973, 6.1514) /0.696	0.7038 (-2.8178, 4.2255) /0.695	1.3425 (0.3059, 5.8930) /0.696	
Rest of World	3/ 70 (4%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertension						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	4/145 (3%)	0/146	>999 (>999, >999) /NC	5.0157 (-11.8696, 21.9009) /0.560	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Hypertensive crisis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Orthostatic hypotension						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	
Phlebitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Varicophlebitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Varicose vein						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Venous thrombosis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	0.180
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	3/ 70 (4%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	0.243
Europe	3/145 (2%)	1/146 (<1%)	3.0634 (0.3149, 29.7994) /0.335	1.3840 (-1.2913, 4.0594) /0.311	3.0207 (0.3179, 28.7018) /0.336	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematuria						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Micturition urgency						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Proteinuria						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal impairment						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
North America	2/ 93 (2%)	2/107 (2%)	1.1538 (0.1593, 8.3567) /0.887	0.2814 (-3.6272, 4.1900) /0.888	1.1505 (0.1653, 8.0076) /0.887	NC
Europe	4/145 (3%)	0/146	>999 (>999, >999) /NC	5.0157 (-11.8696, 21.9009) /0.560	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinnitus						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Deafness						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear discomfort						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Ear pain						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Excessive cerumen production						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.109
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	3/ 55 (5%)	0.2512 (0.0254, 2.4847) /0.237	-4.0260 (-10.6401, 2.5882) /0.233	0.2619 (0.0280, 2.4490) /0.240	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Anogenital warts						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.217
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fibrous histiocytoma						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Knuckle pads						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	
Melanocytic naevus						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bradycardia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Cardiovascular disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Palpitations						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Sinus tachycardia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ventricular extrasystoles						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.120
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Allergy to animal						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Mycotic allergy						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypogonadism						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Hypothyroidism						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thyroid mass						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Social circumstances						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menopause						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Stress at work						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Biliary tract disorder						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion missed						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental implantation						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	47/ 93 (51%)	29/107 (27%)	2.7481 (1.5248, 4.9528) /<.001	23.4348 (10.2369, 36.6327) /<.001	1.8647 (1.2878, 2.6999) /<.001	0.632
Europe	71/145 (49%)	39/146 (27%)	2.6324 (1.6121, 4.2982) /<.001	22.2532 (11.4036, 33.1028) /<.001	1.8331 (1.3365, 2.5141) /<.001	
Rest of World	40/ 70 (57%)	13/ 55 (24%)	4.3077 (1.9713, 9.4130) /<.001	33.5065 (17.3677, 49.6453) /<.001	2.4176 (1.4423, 4.0524) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	16/ 93 (17%)	17/107 (16%)	1.1001 (0.5210, 2.3229) /0.802	1.3165 (-9.0187, 11.6516) /0.803	1.0829 (0.5804, 2.0202) /0.802	0.342
Europe	25/145 (17%)	26/146 (18%)	0.9615 (0.5253, 1.7600) /0.899	-0.5668 (-9.3026, 8.1689) /0.899	0.9682 (0.5880, 1.5940) /0.899	
Rest of World	17/ 70 (24%)	7/ 55 (13%)	2.1995 (0.8397, 5.7613) /0.109	11.5584 (-1.8015, 24.9184) /0.090	1.9082 (0.8521, 4.2733) /0.116	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
North America	3/ 93 (3%)	2/107 (2%)	1.7500 (0.2860, 10.7062) /0.545	1.3566 (-3.0569, 5.7702) /0.547	1.7258 (0.2947, 10.1065) /0.545	0.212
Europe	5/145 (3%)	0/146	>999 (>999, >999) /NC	5.6819 (-11.2187, 22.5824) /0.510	>999 (>999, >999) /NC	
Rest of World	4/ 70 (6%)	1/ 55 (2%)	3.2727 (0.3552, 30.1518) /0.295	3.8961 (-2.5873, 10.3795) /0.239	3.1429 (0.3615, 27.3248) /0.299	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Upper respiratory tract infection						
North America	4/ 93 (4%)	1/107 (<1%)	4.7640 (0.5230, 43.3995) /0.166	3.3665 (-1.1419, 7.8749) /0.143	4.6022 (0.5236, 40.4530) /0.169	0.916
Europe	0/145	0/146	NC	NC	NC	
Rest of World	3/ 70 (4%)	1/ 55 (2%)	2.4179 (0.2445, 23.9097) /0.450	2.4675 (-3.4468, 8.3819) /0.414	2.3571 (0.2521, 22.0408) /0.452	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	4/146 (3%)	<0.0001 (<0.0001, -) />0.999	-4.9973 (-21.9315, 11.9368) /0.563	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	3/145 (2%)	4/146 (3%)	0.7500 (0.1649, 3.4118) /0.710	-0.6708 (-4.1891, 2.8476) /0.709	0.7552 (0.1720, 3.3148) /0.710	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis						
North America	0/ 93	3/107 (3%)	<0.0001 (<0.0001, -) />0.999	-5.0594 (-26.1046, 15.9858) /0.638	<0.0001 (<0.0001, -) />0.999	0.126
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	2/ 70 (3%)	1/ 55 (2%)	1.5882 (0.1403, 17.9846) /0.709	1.0390 (-4.2241, 6.3020) /0.699	1.5714 (0.1463, 16.8832) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract infection						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	0.109
Europe	0/145	2/146 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6449 (-20.6173, 13.3275) /0.674	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Gonorrhoea						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinusitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Syphilis						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.998
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	3/145 (2%)	2/146 (1%)	1.5211 (0.2504, 9.2405) /0.649	0.6991 (-2.2880, 3.6862) /0.646	1.5103 (0.2561, 8.9059) /0.649	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Acute sinusitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Tinea versicolour						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Candida infection						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Cellulitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	0.298
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	0.747
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Onychomycosis						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis media						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	
Proctitis gonococcal						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth infection						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tracheitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal chlamydia infection						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body tinea						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cystitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site cellulitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal gonococcal infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis media acute						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Secondary syphilis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal infection						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Tooth abscess						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis gonococcal						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal infection						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Orchitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Anal abscess						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervicitis human papilloma virus						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Folliculitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Groin abscess						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Hepatitis A						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infected bite						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Liver abscess						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Localised infection						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral candidiasis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Periodontitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pertussis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Proctitis chlamydial						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis herpes						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rotavirus infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Tinea infection						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
North America	34/ 93 (37%)	3/107 (3%)	19.9774 (5.8808, 67.8646) /<.001	33.7554 (23.4799, 44.0309) /<.001	13.0393 (4.1400, 41.0690) /<.001	NC
Europe	46/145 (32%)	1/146 (<1%)	67.3737 (9.1403, 496.6170) /<.001	31.0392 (23.3468, 38.7316) /<.001	46.3172 (6.4736, 331.3899) /<.001	
Rest of World	26/ 70 (37%)	1/ 55 (2%)	31.9091 (4.1633, 244.5619) /<.001	35.3247 (23.4675, 47.1818) /<.001	20.4286 (2.8608, 145.8770) /0.003	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
North America	29/ 93 (31%)	0/107	>999 (>999, >999) /NC	32.0991 (10.8760, 53.3221) /0.003	>999 (>999, >999) /NC	NC
Europe	37/145 (26%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	25/ 70 (36%)	0/ 55	>999 (>999, >999) /NC	36.4100 (7.6602, 65.1597) /0.013	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site module						
North America	3/ 93 (3%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyrexia						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	7/145 (5%)	0/146	>999 (>999, >999) /NC	7.0056 (-9.9454, 23.9566) /0.418	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	>0.999
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site erythema						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Chills						
North America	3/ 93 (3%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Discomfort						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oedema peripheral						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral swelling						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vessel puncture site pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	11/ 93 (12%)	8/107 (7%)	1.6601 (0.6378, 4.3208) /0.299	4.3513 (-3.8896, 12.5923) /0.301	1.5820 (0.6646, 3.7659) /0.300	>0.999
Europe	8/145 (6%)	5/146 (3%)	1.6467 (0.5257, 5.1583) /0.392	2.0926 (-2.6521, 6.8373) /0.387	1.6110 (0.5398, 4.8083) /0.393	
Rest of World	4/ 70 (6%)	2/ 55 (4%)	1.6061 (0.2832, 9.1086) /0.593	2.0779 (-5.2734, 9.4292) /0.580	1.5714 (0.2987, 8.2665) /0.594	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diarrhoea						
North America	5/ 93 (5%)	2/107 (2%)	2.9830 (0.5649, 15.7529) /0.198	3.5072 (-1.7463, 8.7606) /0.191	2.8763 (0.5714, 14.4780) /0.200	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nausea						
North America	2/ 93 (2%)	3/107 (3%)	0.7619 (0.1245, 4.6611) /0.769	-0.6532 (-4.9515, 3.6451) /0.766	0.7670 (0.1310, 4.4918) /0.769	0.218
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Toothache						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Haemorrhoids						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
North America	0/ 93	3/107 (3%)	<0.0001 (<0.0001, -) />0.999	-5.0594 (-26.1046, 15.9858) /0.638	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Gastritis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal fissure						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Enteritis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Food poisoning						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Inguinal hernia						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Odynophagia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis						
North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental caries						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal hernia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilic oesophagitis						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Functional gastrointestinal disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Irritable bowel syndrome						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis chronic						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis ulcerative						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rectal haemorrhage						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
North America	6/ 93 (6%)	7/107 (7%)	0.9852 (0.3190, 3.0427) /0.979	-0.0904 (-6.9374, 6.7565) /0.979	0.9862 (0.3436, 2.8306) /0.979	0.502
Europe	11/145 (8%)	5/146 (3%)	2.3149 (0.7836, 6.8389) /0.129	4.1615 (-1.0610, 9.3841) /0.118	2.2152 (0.7894, 6.2163) /0.131	
Rest of World	4/ 70 (6%)	3/ 55 (5%)	1.0505 (0.2251, 4.9023) /0.950	0.2597 (-7.8388, 8.3583) /0.950	1.0476 (0.2446, 4.4871) /0.950	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Back pain						
North America	3/ 93 (3%)	1/107 (<1%)	3.5333 (0.3612, 34.5630) /0.278	2.2912 (-1.7360, 6.3185) /0.265	3.4516 (0.3652, 32.6189) /0.280	0.366
Europe	6/145 (4%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Myalgia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	2/ 70 (3%)	1/ 55 (2%)	1.5882 (0.1403, 17.9846) /0.709	1.0390 (-4.2241, 6.3020) /0.699	1.5714 (0.1463, 16.8832) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pain in extremity						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	0.281
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal pain						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	0.997
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Muscle contracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Neck pain						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Musculoskeletal chest pain						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteoarthritis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropathy						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint effusion						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Myositis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteonecrosis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Polyarthrititis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Spinal osteoarthritis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
North America	5/ 93 (5%)	6/107 (6%)	0.9564 (0.2822, 3.2421) /0.943	-0.2311 (-6.5570, 6.0947) /0.943	0.9588 (0.3024, 3.0396) /0.943	0.631
Europe	6/145 (4%)	3/146 (2%)	2.0576 (0.5046, 8.3892) /0.314	2.0831 (-1.8923, 6.0586) /0.304	2.0138 (0.5134, 7.8990) /0.315	
Rest of World	3/ 70 (4%)	1/ 55 (2%)	2.4179 (0.2445, 23.9097) /0.450	2.4675 (-3.4468, 8.3819) /0.414	2.3571 (0.2521, 22.0408) /0.452	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
North America	2/ 93 (2%)	3/107 (3%)	0.7619 (0.1245, 4.6611) /0.769	-0.6532 (-4.9515, 3.6451) /0.766	0.7670 (0.1310, 4.4918) /0.769	0.314
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Sciatica						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervicobrachial syndrome						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Syncope						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Burning sensation						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cerebrovascular accident						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysgeusia						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intercostal neuralgia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contractions involuntary						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neuromuscular blockade						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post-traumatic headache						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	4/ 93 (4%)	5/107 (5%)	0.9169 (0.2388, 3.5197) /0.899	-0.3718 (-6.1159, 5.3722) /0.899	0.9204 (0.2546, 3.3273) /0.899	0.084
Europe	2/145 (1%)	3/146 (2%)	0.6667 (0.1097, 4.0499) /0.660	-0.6755 (-3.6586, 2.3077) /0.657	0.6713 (0.1138, 3.9582) /0.660	
Rest of World	0/ 70	4/ 55 (7%)	<0.0001 (<0.0001, -) />0.999	-9.3414 (-34.2932, 15.6104) /0.463	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cough						
North America	2/ 93 (2%)	2/107 (2%)	1.1538 (0.1593, 8.3567) /0.887	0.2814 (-3.6272, 4.1900) /0.888	1.1505 (0.1653, 8.0076) /0.887	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	2/146 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6449 (-20.6173, 13.3275) /0.674	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Catarrh						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Productive cough						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract congestion						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract congestion						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	
Bronchospasm						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lung disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Nasal septum deviation						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pneumonitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory distress						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wheezing						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.448
Europe	3/145 (2%)	2/146 (1%)	1.5211 (0.2504, 9.2405) /0.649	0.6991 (-2.2880, 3.6862) /0.646	1.5103 (0.2561, 8.9059) /0.649	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Pruritus						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Urticaria						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Decubitus ulcer						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Intertrigo						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash erythematous						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash maculo-papular						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	7/ 93 (8%)	5/107 (5%)	1.6605 (0.5087, 5.4198) /0.401	2.8540 (-3.8350, 9.5430) /0.403	1.6108 (0.5290, 4.9047) /0.401	0.063
Europe	9/145 (6%)	1/146 (<1%)	9.5956 (1.1998, 76.7453) /0.033	5.5220 (1.3731, 9.6708) /0.009	9.0621 (1.1629, 70.6163) /0.035	
Rest of World	2/ 70 (3%)	3/ 55 (5%)	0.5098 (0.0822, 3.1630) /0.469	-2.5974 (-9.7564, 4.5615) /0.477	0.5238 (0.0907, 3.0264) /0.470	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Contusion						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Arthropod bite						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Epicondylitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exposure to communicable disease						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Procedural pain						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection related reaction						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Radius fracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Road traffic accident						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Upper limb fracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Facial bones fracture						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Foot fracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Humerus fracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Injury corneal						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint dislocation						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament rupture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Meniscus injury						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin injury						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Tendon rupture						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth fracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
North America	4/ 93 (4%)	4/107 (4%)	1.1573 (0.2812, 4.7623) /0.840	0.5628 (-4.9073, 6.0328) /0.840	1.1505 (0.2960, 4.4727) /0.840	0.291
Europe	2/145 (1%)	3/146 (2%)	0.6667 (0.1097, 4.0499) /0.660	-0.6755 (-3.6586, 2.3077) /0.657	0.6713 (0.1138, 3.9582) /0.660	
Rest of World	6/ 70 (9%)	1/ 55 (2%)	5.0625 (0.5910, 43.3635) /0.139	6.7532 (-0.6949, 14.2014) /0.076	4.7143 (0.5847, 38.0133) /0.145	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Insomnia						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.998
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Sleep disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depression						
North America	2/ 93 (2%)	3/107 (3%)	0.7619 (0.1245, 4.6611) /0.769	-0.6532 (-4.9515, 3.6451) /0.766	0.7670 (0.1310, 4.4918) /0.769	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depression suicidal						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Drug dependence						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Suicidal behaviour						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicide attempt						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
North America	2/ 93 (2%)	4/107 (4%)	0.5659 (0.1013, 3.1625) /0.517	-1.5878 (-6.2366, 3.0610) /0.503	0.5753 (0.1078, 3.0696) /0.518	0.879
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	1/ 70 (1%)	2/ 55 (4%)	0.3841 (0.0339, 4.3494) /0.440	-2.2078 (-7.8825, 3.4669) /0.446	0.3929 (0.0366, 4.2208) /0.441	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D deficiency						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Decreased appetite						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Dehydration						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetes mellitus						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetic ketoacidosis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypokalaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	
Hypophosphataemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin B6 deficiency						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	4/ 93 (4%)	1/107 (<1%)	4.7640 (0.5230, 43.3995) /0.166	3.3665 (-1.1419, 7.8749) /0.143	4.6022 (0.5236, 40.4530) /0.169	0.321
Europe	4/145 (3%)	5/146 (3%)	0.8000 (0.2105, 3.0410) /0.743	-0.6660 (-4.6421, 3.3100) /0.743	0.8055 (0.2207, 2.9396) /0.743	
Rest of World	1/ 70 (1%)	1/ 55 (2%)	0.7826 (0.0478, 12.8003) /0.864	-0.3896 (-4.8836, 4.1044) /0.865	0.7857 (0.0503, 12.2810) /0.863	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Alanine aminotransferase increased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatine phosphokinase increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Creatinine renal clearance decreased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.240
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aspartate aminotransferase increased						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood cholesterol increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	2/146 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6449 (-20.6173, 13.3275) /0.674	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D decreased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

ECG signs of ventricular hypertrophy						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neisseria test positive						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye disorders						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lacrimation increased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitreous haematoma						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	2/146 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6449 (-20.6173, 13.3275) /0.674	<0.0001 (<0.0001, -) />0.999	
Rest of World	2/ 70 (3%)	1/ 55 (2%)	1.5882 (0.1403, 17.9846) /0.709	1.0390 (-4.2241, 6.3020) /0.699	1.5714 (0.1463, 16.8832) /0.709	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	2/ 70 (3%)	1/ 55 (2%)	1.5882 (0.1403, 17.9846) /0.709	1.0390 (-4.2241, 6.3020) /0.699	1.5714 (0.1463, 16.8832) /0.709	
Anaemia folate deficiency						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Thrombocytopeni						
^a North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Reproductive system and breast disorders						
Any Event						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	0.459
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Benign prostatic hyperplasia						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menorrhagia						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Balanoposthitis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical dysplasia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Adenomyosis						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast mass						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Genital erythema						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vascular disorders						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	0.141
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	4/ 70 (6%)	1/ 55 (2%)	3.2727 (0.3552, 30.1518) /0.295	3.8961 (-2.5873, 10.3795) /0.239	3.1429 (0.3615, 27.3248) /0.299	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertension						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	4/ 70 (6%)	1/ 55 (2%)	3.2727 (0.3552, 30.1518) /0.295	3.8961 (-2.5873, 10.3795) /0.239	3.1429 (0.3615, 27.3248) /0.299	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deep vein thrombosis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	0.298
Europe	2/145 (1%)	2/146 (1%)	1.0070 (0.1399, 7.2467) /0.994	0.0094 (-2.6661, 2.6850) /0.994	1.0069 (0.1438, 7.0521) /0.994	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal impairment						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal colic						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral discharge						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Basal cell carcinoma						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	
Skin papilloma						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Squamous cell carcinoma of skin						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Allergy to animal						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Drug hypersensitivity						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidism						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis acute						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abortion spontaneous						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	11/ 93 (12%)	8/107 (7%)	1.6601 (0.6378, 4.3208) /0.299	4.3513 (-3.8896, 12.5923) /0.301	1.5820 (0.6646, 3.7659) /0.300	0.335
Europe	12/145 (8%)	6/146 (4%)	2.1053 (0.7681, 5.7704) /0.148	4.1663 (-1.3545, 9.6871) /0.139	2.0138 (0.7767, 5.2209) /0.150	
Rest of World	4/ 70 (6%)	5/ 55 (9%)	0.6061 (0.1547, 2.3736) /0.472	-3.3766 (-12.7195, 5.9663) /0.479	0.6286 (0.1771, 2.2304) /0.472	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.120
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Anal abscess						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis A						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Appendicitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
North America	5/ 93 (5%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	5/145 (3%)	0/146	>999 (>999, >999) /NC	5.6819 (-11.2187, 22.5824) /0.510	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
North America	4/ 93 (4%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	5/145 (3%)	0/146	>999 (>999, >999) /NC	5.6819 (-11.2187, 22.5824) /0.510	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Injection site induration						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.168
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	
Nausea						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vomiting						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	
Abdominal pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Colitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis acute						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Rhabdomyolysis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seizure						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Animal bite						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	
Eye injury						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Depression						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anxiety disorder						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertriglyceridaemia						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	3/ 93 (3%)	2/107 (2%)	1.7500 (0.2860, 10.7062) /0.545	1.3566 (-3.0569, 5.7702) /0.547	1.7258 (0.2947, 10.1065) /0.545	0.318
Europe	4/145 (3%)	2/146 (1%)	2.0426 (0.3683, 11.3293) /0.414	1.3888 (-1.8765, 4.6540) /0.405	2.0138 (0.3747, 10.8241) /0.415	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lipase increased						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood cholesterol increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood triglycerides increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood glucose increased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood phosphorus decreased						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatinine increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood triglycerides						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Liver function test abnormal						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst ruptured						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic kidney disease						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Papillary thyroid cancer						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Seminoma						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	1/ 93 (1%)	2/107 (2%)	0.5707 (0.0509, 6.3964) /0.649	-0.7939 (-4.1073, 2.5195) /0.639	0.5753 (0.0530, 6.2426) /0.649	0.061
Europe	7/145 (5%)	1/146 (<1%)	7.3551 (0.8933, 60.5581) /0.064	4.1427 (0.4061, 7.8792) /0.030	7.0483 (0.8782, 56.5674) /0.066	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	2/145 (1%)	1/146 (<1%)	2.0280 (0.1819, 22.6142) /0.566	0.6944 (-1.6280, 3.0168) /0.558	2.0138 (0.1846, 21.9650) /0.566	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Acute hepatitis B						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis						
C North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Pyelonephritis acute						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	4/145 (3%)	0/146	>999 (>999, >999) /NC	5.0157 (-11.8696, 21.9009) /0.560	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatine phosphokinase increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lipase increased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood bilirubin increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Transaminases increased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neutropenia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Squamous cell carcinoma						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	
Hyperbilirubinaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 5

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 5

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS

Maximum Toxicity Grade= 5

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
PI	22/ 51 (43%)	20/ 54 (37%)	1.2897 (0.5898, 2.8201) /0.524	6.1002 (-12.6255, 24.8259) /0.523	1.1647 (0.7285, 1.8622) /0.524	0.200
INI	40/102 (39%)	40/ 99 (40%)	0.9516 (0.5409, 1.6742) /0.863	-1.1884 (-14.7237, 12.3470) /0.863	0.9706 (0.6908, 1.3636) /0.863	
NNRTI	39/155 (25%)	55/155 (35%)	0.6113 (0.3746, 0.9976) /0.049	-10.3226 (-20.4914, -0.1537) /0.047	0.7091 (0.5024, 1.0009) /0.051	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
PI	20/ 51 (39%)	18/ 54 (33%)	1.2903 (0.5812, 2.8647) /0.531	5.8824 (-12.4924, 24.2571) /0.530	1.1765 (0.7072, 1.9571) /0.531	0.820
INI	46/102 (45%)	37/ 99 (37%)	1.3764 (0.7832, 2.4189) /0.267	7.7243 (-5.8429, 21.2915) /0.264	1.2067 (0.8649, 1.6834) /0.269	
NNRTI	59/155 (38%)	56/155 (36%)	1.0865 (0.6852, 1.7228) /0.724	1.9355 (-8.8171, 12.6881) /0.724	1.0536 (0.7883, 1.4081) /0.724	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
PI	5/ 51 (10%)	6/ 54 (11%)	0.8696 (0.2482, 3.0467) /0.827	-1.3072 (-13.0062, 10.3918) /0.827	0.8824 (0.2869, 2.7135) /0.827	0.928
INI	14/102 (14%)	12/ 99 (12%)	1.1534 (0.5049, 2.6346) /0.735	1.6043 (-7.6655, 10.8741) /0.734	1.1324 (0.5513, 2.3258) /0.735	
NNRTI	21/155 (14%)	21/155 (14%)	1.0000 (0.5218, 1.9166) />0.999	<0.0001 (-7.6195, 7.6195) />0.999	1.0000 (0.5698, 1.7549) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.126
INI	14/102 (14%)	8/ 99 (8%)	1.8097 (0.7235, 4.5262) /0.205	5.6447 (-2.9238, 14.2132) /0.197	1.6985 (0.7455, 3.8699) /0.207	
NNRTI	10/155 (6%)	15/155 (10%)	0.6437 (0.2798, 1.4808) /0.300	-3.2258 (-9.2773, 2.8257) /0.296	0.6667 (0.3091, 1.4378) /0.301	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.170
INI	7/102 (7%)	7/ 99 (7%)	0.9684 (0.3269, 2.8693) /0.954	-0.2080 (-7.2485, 6.8325) /0.954	0.9706 (0.3533, 2.6662) /0.954	
NNRTI	8/155 (5%)	2/155 (1%)	4.1633 (0.8697, 19.9302) /0.074	3.8710 (-0.0390, 7.7809) /0.052	4.0000 (0.8632, 18.5358) /0.076	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
PI	2/ 51 (4%)	4/ 54 (7%)	0.5102 (0.0893, 2.9141) /0.449	-3.4858 (-12.2706, 5.2989) /0.437	0.5294 (0.1013, 2.7668) /0.451	0.724
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	7/155 (5%)	6/155 (4%)	1.1745 (0.3856, 3.5779) /0.777	0.6452 (-3.8168, 5.1072) /0.777	1.1667 (0.4012, 3.3926) /0.777	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
PI	6/ 51 (12%)	4/ 54 (7%)	1.6667 (0.4418, 6.2873) /0.451	4.3573 (-6.9113, 15.6259) /0.449	1.5882 (0.4756, 5.3042) /0.452	0.021
INI	0/102	4/ 99 (4%)	<0.0001 (<0.0001, -) />0.999	-6.2511 (-26.5133, 14.0111) /0.545	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	5/155 (3%)	0.1948 (0.0225, 1.6871) /0.138	-2.5806 (-5.6344, 0.4731) /0.098	0.2000 (0.0236, 1.6922) /0.140	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis						
PI	2/ 51 (4%)	1/ 54 (2%)	2.1633 (0.1901, 24.6136) /0.534	2.0697 (-4.3575, 8.4970) /0.528	2.1176 (0.1980, 22.6477) /0.535	0.595
INI	3/102 (3%)	4/ 99 (4%)	0.7197 (0.1569, 3.3011) /0.672	-1.0992 (-6.1782, 3.9797) /0.671	0.7279 (0.1672, 3.1697) /0.672	
NNRTI	4/155 (3%)	2/155 (1%)	2.0265 (0.3657, 11.2291) /0.419	1.2903 (-1.7736, 4.3542) /0.409	2.0000 (0.3717, 10.7603) /0.419	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.136
INI	1/102 (<1%)	3/ 99 (3%)	0.3168 (0.0324, 3.0986) /0.323	-2.0499 (-5.9304, 1.8306) /0.300	0.3235 (0.0342, 3.0580) /0.325	
NNRTI	8/155 (5%)	3/155 (2%)	2.7574 (0.7176, 10.5953) /0.140	3.2258 (-0.8773, 7.3289) /0.123	2.6667 (0.7209, 9.8643) /0.142	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	4/ 99 (4%)	0.4750 (0.0850, 2.6538) /0.396	-2.0796 (-6.8002, 2.6410) /0.388	0.4853 (0.0909, 2.5901) /0.397	
NNRTI	3/155 (2%)	5/155 (3%)	0.5921 (0.1390, 2.5217) /0.478	-1.2903 (-4.8175, 2.2368) /0.473	0.6000 (0.1459, 2.4673) /0.479	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.413
INI	3/102 (3%)	3/ 99 (3%)	0.9697 (0.1910, 4.9233) /0.970	-0.0891 (-4.7958, 4.6176) /0.970	0.9706 (0.2007, 4.6944) /0.970	
NNRTI	1/155 (<1%)	5/155 (3%)	0.1948 (0.0225, 1.6871) /0.138	-2.5806 (-5.6344, 0.4731) /0.098	0.2000 (0.0236, 1.6922) /0.140	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Lower respiratory tract infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	6/155 (4%)	4/155 (3%)	1.5201 (0.4204, 5.4961) /0.523	1.2903 (-2.6407, 5.2214) /0.520	1.5000 (0.4317, 5.2115) /0.523	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	4/102 (4%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	3/155 (2%)	0.6623 (0.1091, 4.0197) /0.654	-0.6452 (-3.4488, 2.1585) /0.652	0.6667 (0.1130, 3.9347) /0.654	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.369
INI	4/102 (4%)	3/ 99 (3%)	1.3061 (0.2848, 5.9909) /0.731	0.8913 (-4.1676, 5.9501) /0.730	1.2941 (0.2972, 5.6351) /0.731	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.875
INI	1/102 (<1%)	2/ 99 (2%)	0.4802 (0.0428, 5.3818) /0.552	-1.0398 (-4.4068, 2.3272) /0.545	0.4853 (0.0447, 5.2671) /0.552	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.683
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	4/155 (3%)	1/155 (<1%)	4.0795 (0.4508, 36.9195) /0.211	1.9355 (-0.8608, 4.7318) /0.175	4.0000 (0.4522, 35.3840) /0.213	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	5/ 99 (5%)	<0.0001 (<0.0001, -) />0.999	-7.2190 (-27.5306, 13.0926) /0.486	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	3/ 99 (3%)	0.6400 (0.1046, 3.9145) /0.629	-1.0695 (-5.3871, 3.2481) /0.627	0.6471 (0.1105, 3.7900) /0.629	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	2/155 (1%)	1.5099 (0.2488, 9.1636) /0.654	0.6452 (-2.1585, 3.4488) /0.652	1.5000 (0.2542, 8.8530) /0.654	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis viral						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	3/102 (3%)	1/ 99 (1%)	2.9697 (0.3037, 29.0436) /0.350	1.9311 (-1.8940, 5.7561) /0.322	2.9118 (0.3081, 27.5217) /0.351	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	4/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	3/155 (2%)	1/155 (<1%)	3.0395 (0.3127, 29.5452) /0.338	1.2903 (-1.2182, 3.7988) /0.313	3.0000 (0.3155, 28.5257) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute sinusitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea cruris						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Tinea versicolour						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Candida infection						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic tonsillitis						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Fungal infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impetigo PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychomycosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pulpitis dental						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis chlamydial						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Acarodermatitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amoebiasis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Anal chlamydia infection PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anorectal human papilloma virus infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Clostridium difficile colitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis bacterial						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Cystitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
<hr/>						
Ear infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis infectious						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epididymitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Gastric infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal viral infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes virus infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection parasitic						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site cellulitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Nasal herpes PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis media acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia mycoplasmal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Primary syphilis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sexually transmitted disease						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Skin candida						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
<hr/>						
Staphylococcal infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Tinea pedis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tongue fungal infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ureaplasma infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral tonsillitis						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal candidiasis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginitis trichomonal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
PI	27/ 51 (53%)	2/ 54 (4%)	29.2499 (6.4257, 133.1450) /<.001	49.2375 (34.6420, 63.8329) /<.001	14.2941 (3.5803, 57.0677) /<.001	NC
INI	43/102 (42%)	7/ 99 (7%)	9.5787 (4.0407, 22.7068) /<.001	35.0862 (24.2541, 45.9182) /<.001	5.9622 (2.8179, 12.6148) /<.001	
NNRTI	65/155 (42%)	8/155 (5%)	13.2708 (6.0846, 28.9443) /<.001	36.7742 (28.2608, 45.2876) /<.001	8.1250 (4.0356, 16.3584) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site pain PI	28/ 51 (55%)	0/ 54	>999 (>999, >999) /NC	54.6627 (24.6925, 84.6329) /<.001	>999 (>999, >999) /NC	NC
INI	38/102 (37%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	64/155 (41%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
PI	11/ 51 (22%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	11/102 (11%)	0/ 99	>999 (>999, >999) /NC	12.6881 (-8.1898, 33.5660) /0.234	>999 (>999, >999) /NC	
NNRTI	11/155 (7%)	0/155	>999 (>999, >999) /NC	9.1736 (-7.3722, 25.7194) /0.277	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue PI	3/ 51 (6%)	1/ 54 (2%)	3.3125 (0.3332, 32.9279) /0.307	4.0305 (-3.3608, 11.4218) /0.285	3.1765 (0.3414, 29.5579) /0.310	0.460
INI	10/102 (10%)	1/ 99 (1%)	10.6522 (1.3371, 84.8588) /0.025	8.7938 (2.6960, 14.8916) /0.005	9.7059 (1.2659, 74.4164) /0.029	
NNRTI	7/155 (5%)	3/155 (2%)	2.3964 (0.6081, 9.4430) /0.212	2.5806 (-1.3425, 6.5038) /0.197	2.3333 (0.6146, 8.8583) /0.213	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.118
INI	4/102 (4%)	5/ 99 (5%)	0.7673 (0.1999, 2.9449) /0.700	-1.1289 (-6.8558, 4.5980) /0.699	0.7765 (0.2147, 2.8077) /0.700	
NNRTI	12/155 (8%)	3/155 (2%)	4.2517 (1.1756, 15.3777) /0.027	5.8065 (1.0730, 10.5399) /0.016	4.0000 (1.1513, 13.8974) /0.029	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
PI	5/ 51 (10%)	0/ 54	>999 (>999, >999) /NC	11.7542 (-16.5766, 40.0850) /0.416	>999 (>999, >999) /NC	NC
INI	4/102 (4%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	11/155 (7%)	0/155	>999 (>999, >999) /NC	9.1736 (-7.3722, 25.7194) /0.277	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
PI	3/ 51 (6%)	0/ 54	>999 (>999, >999) /NC	8.0142 (-19.9986, 36.0271) /0.575	>999 (>999, >999) /NC	NC
INI	4/102 (4%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	9/155 (6%)	0/155	>999 (>999, >999) /NC	7.9417 (-8.5463, 24.4298) /0.345	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
PI	7/ 51 (14%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	4/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
PI	0/ 51	0/ 54	NC	NC	NC	0.313
INI	1/102 (<1%)	2/ 99 (2%)	0.4802 (0.0428, 5.3818) /0.552	-1.0398 (-4.4068, 2.3272) /0.545	0.4853 (0.0447, 5.2671) /0.552	
NNRTI	5/155 (3%)	1/155 (<1%)	5.1333 (0.5927, 44.4572) /0.138	2.5806 (-0.4731, 5.6344) /0.098	5.0000 (0.5910, 42.3046) /0.140	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site bruising						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	4/102 (4%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	4/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site pruritus						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	5/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site warmth						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	4/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	4/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haematoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	3/102 (3%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site reaction						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cyst PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Discomfort PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling of body temperature change						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site anaesthesia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site discolouration						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Oedema peripheral						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
PI	7/ 51 (14%)	1/ 54 (2%)	8.4318 (0.9989, 71.1714) /0.050	11.8736 (1.7680, 21.9793) /0.021	7.4118 (0.9446, 58.1550) /0.057	0.181
INI	15/102 (15%)	9/ 99 (9%)	1.7241 (0.7170, 4.1458) /0.224	5.6150 (-3.2905, 14.5205) /0.217	1.6176 (0.7425, 3.5245) /0.226	
NNRTI	26/155 (17%)	19/155 (12%)	1.4427 (0.7617, 2.7325) /0.261	4.5161 (-3.3104, 12.3427) /0.258	1.3684 (0.7910, 2.3672) /0.262	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.219
INI	4/102 (4%)	7/ 99 (7%)	0.5364 (0.1520, 1.8931) /0.333	-3.1491 (-9.4488, 3.1506) /0.327	0.5546 (0.1676, 1.8358) /0.334	
NNRTI	9/155 (6%)	6/155 (4%)	1.5308 (0.5315, 4.4093) /0.430	1.9355 (-2.8371, 6.7080) /0.427	1.5000 (0.5470, 4.1131) /0.431	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.520
INI	3/102 (3%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	5/155 (3%)	1/155 (<1%)	5.1333 (0.5927, 44.4572) /0.138	2.5806 (-0.4731, 5.6344) /0.098	5.0000 (0.5910, 42.3046) /0.140	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.252
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	2/155 (1%)	1.5099 (0.2488, 9.1636) /0.654	0.6452 (-2.1585, 3.4488) /0.652	1.5000 (0.2542, 8.8530) /0.654	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache PI	0/ 51	0/ 54	NC	NC	NC	0.544
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	1/155 (<1%)	3/155 (2%)	0.3290 (0.0338, 3.1981) /0.338	-1.2903 (-3.7988, 1.2182) /0.313	0.3333 (0.0351, 3.1695) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.352
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.538
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.222
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.316
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aphthous ulcer						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Gastritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal distension						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Anal fissure						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal pruritus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal skin tags						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anorectal discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Chronic gastritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphagia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Enteritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epigastric discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids thrombosed						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Lip dry						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Lip swelling						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Mouth ulceration						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Odynophagia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Oral disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral pain PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Proctitis PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Steatorrhoea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue ulceration						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth impacted						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Umbilical hernia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
PI	5/ 51 (10%)	2/ 54 (4%)	2.8261 (0.5230, 15.2719) /0.227	6.1002 (-3.4903, 15.6907) /0.213	2.6471 (0.5374, 13.0396) /0.231	0.850
INI	19/102 (19%)	11/ 99 (11%)	1.8313 (0.8222, 4.0791) /0.139	7.5163 (-2.2514, 17.2841) /0.132	1.6765 (0.8416, 3.3396) /0.142	
NNRTI	23/155 (15%)	14/155 (9%)	1.7549 (0.8666, 3.5534) /0.118	5.8065 (-1.3826, 12.9955) /0.113	1.6429 (0.8785, 3.0723) /0.120	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain PI	2/ 51 (4%)	1/ 54 (2%)	2.1633 (0.1901, 24.6136) /0.534	2.0697 (-4.3575, 8.4970) /0.528	2.1176 (0.1980, 22.6477) /0.535	0.831
INI	5/102 (5%)	5/ 99 (5%)	0.9691 (0.2717, 3.4564) /0.961	-0.1485 (-6.1622, 5.8651) /0.961	0.9706 (0.2899, 3.2495) /0.961	
NNRTI	4/155 (3%)	3/155 (2%)	1.3422 (0.2954, 6.0987) /0.703	0.6452 (-2.6616, 3.9519) /0.702	1.3333 (0.3034, 5.8590) /0.703	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	4/155 (3%)	7/155 (5%)	0.5601 (0.1606, 1.9533) /0.363	-1.9355 (-6.0486, 2.1776) /0.356	0.5714 (0.1707, 1.9127) /0.364	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.767
INI	4/102 (4%)	1/ 99 (1%)	4.0000 (0.4392, 36.4309) /0.219	2.9115 (-1.3394, 7.1623) /0.179	3.8824 (0.4416, 34.1318) /0.221	
NNRTI	3/155 (2%)	1/155 (<1%)	3.0395 (0.3127, 29.5452) /0.338	1.2903 (-1.2182, 3.7988) /0.313	3.0000 (0.3155, 28.5257) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.047
INI	0/102	4/ 99 (4%)	<0.0001 (<0.0001, -) />0.999	-6.2511 (-26.5133, 14.0111) /0.545	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.597
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	2/155 (1%)	3/155 (2%)	0.6623 (0.1091, 4.0197) /0.654	-0.6452 (-3.4488, 2.1585) /0.652	0.6667 (0.1130, 3.9347) /0.654	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint swelling						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal pain PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bursitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot deformity						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc protrusion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteopenia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	
Arthritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Costochondritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Dupuytren's contracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exostosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Flank pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle tightness						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Patellofemoral pain syndrome						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Scoliosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovial cyst						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temporomandibular joint syndrome						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tenosynovitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
PI	13/ 51 (25%)	4/ 54 (7%)	4.2763 (1.2913, 14.1611) /0.017	18.0828 (4.2318, 31.9338) /0.011	3.4412 (1.2003, 9.8660) /0.021	0.485
INI	10/102 (10%)	6/ 99 (6%)	1.6848 (0.5882, 4.8259) /0.331	3.7433 (-3.6994, 11.1861) /0.324	1.6176 (0.6110, 4.2827) /0.333	
NNRTI	25/155 (16%)	14/155 (9%)	1.9368 (0.9653, 3.8859) /0.063	7.0968 (-0.2442, 14.4377) /0.058	1.7857 (0.9652, 3.3036) /0.065	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
PI	7/ 51 (14%)	5/ 54 (9%)	1.5591 (0.4614, 5.2687) /0.475	4.4662 (-7.7388, 16.6713) /0.473	1.4824 (0.5024, 4.3736) /0.476	0.520
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	18/155 (12%)	6/155 (4%)	3.2628 (1.2585, 8.4587) /0.015	7.7419 (1.8546, 13.6293) /0.010	3.0000 (1.2237, 7.3546) /0.016	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.271
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	6/155 (4%)	4/155 (3%)	1.5201 (0.4204, 5.4961) /0.523	1.2903 (-2.6407, 5.2214) /0.520	1.5000 (0.4317, 5.2115) /0.523	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.573
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.256
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuralgia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervicobrachial syndrome						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoaesthesia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Somnolence						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anterograde amnesia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Autonomic nervous system imbalance						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebral cyst PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Cognitive disorder PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Dysaesthesia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dystonia PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Essential tremor						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Facial paralysis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Loss of consciousness						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Memory impairment						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Post herpetic neuralgia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Tension headache						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
PI	3/ 51 (6%)	3/ 54 (6%)	1.0625 (0.2044, 5.5221) /0.943	0.3268 (-8.5629, 9.2165) /0.943	1.0588 (0.2239, 5.0080) /0.943	0.731
INI	9/102 (9%)	9/ 99 (9%)	0.9677 (0.3675, 2.5486) /0.947	-0.2674 (-8.1646, 7.6299) /0.947	0.9706 (0.4019, 2.3437) /0.947	
NNRTI	18/155 (12%)	12/155 (8%)	1.5657 (0.7270, 3.3717) /0.252	3.8710 (-2.6972, 10.4391) /0.248	1.5000 (0.7481, 3.0076) /0.253	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.438
INI	4/102 (4%)	3/ 99 (3%)	1.3061 (0.2848, 5.9909) /0.731	0.8913 (-4.1676, 5.9501) /0.730	1.2941 (0.2972, 5.6351) /0.731	
NNRTI	10/155 (6%)	7/155 (5%)	1.4581 (0.5404, 3.9346) /0.456	1.9355 (-3.1286, 6.9996) /0.454	1.4286 (0.5581, 3.6566) /0.457	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.226
INI	3/102 (3%)	5/ 99 (5%)	0.5697 (0.1324, 2.4504) /0.450	-2.1093 (-7.5277, 3.3090) /0.445	0.5824 (0.1430, 2.3720) /0.451	
NNRTI	6/155 (4%)	3/155 (2%)	2.0403 (0.5010, 8.3085) /0.320	1.9355 (-1.7963, 5.6673) /0.309	2.0000 (0.5093, 7.8542) /0.321	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	4/155 (3%)	0.2451 (0.0271, 2.2184) /0.211	-1.9355 (-4.7318, 0.8608) /0.175	0.2500 (0.0283, 2.2115) /0.213	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus congestion						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.141
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory disorder						
PI	2/ 51 (4%)	1/ 54 (2%)	2.1633 (0.1901, 24.6136) /0.534	2.0697 (-4.3575, 8.4970) /0.528	2.1176 (0.1980, 22.6477) /0.535	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysphonia PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	
Dyspnoea PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Emphysema						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nasal obstruction						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Productive cough						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pulmonary mass						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Reflux laryngitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract congestion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Sleep apnoea syndrome						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
PI	4/ 51 (8%)	1/ 54 (2%)	4.5106 (0.4869, 41.7899) /0.185	5.9913 (-2.2168, 14.1994) /0.153	4.2353 (0.4896, 36.6378) /0.190	0.418
INI	10/102 (10%)	9/ 99 (9%)	1.0870 (0.4219, 2.8001) /0.863	0.7130 (-7.3722, 8.7983) /0.863	1.0784 (0.4577, 2.5410) /0.863	
NNRTI	17/155 (11%)	10/155 (6%)	1.7862 (0.7906, 4.0360) /0.163	4.5161 (-1.7416, 10.7738) /0.157	1.7000 (0.8041, 3.5942) /0.165	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
PI	2/ 51 (4%)	1/ 54 (2%)	2.1633 (0.1901, 24.6136) /0.534	2.0697 (-4.3575, 8.4970) /0.528	2.1176 (0.1980, 22.6477) /0.535	0.977
INI	5/102 (5%)	2/ 99 (2%)	2.5000 (0.4735, 13.1983) /0.280	2.8818 (-2.1419, 7.9054) /0.261	2.4265 (0.4820, 12.2164) /0.282	
NNRTI	3/155 (2%)	1/155 (<1%)	3.0395 (0.3127, 29.5452) /0.338	1.2903 (-1.2182, 3.7988) /0.313	3.0000 (0.3155, 28.5257) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.302
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acne PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash pruritic PI	0/ 51	0/ 54	NC	NC	NC	>0.999
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alopecia PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash generalised						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoeic dermatitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ecchymosis PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Dermatitis PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
<hr/>						
Dermatitis acneiform PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis contact						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nail bed bleeding						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neurodermatitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Onychoclasia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Photosensitivity reaction						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Purpura						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Sebacous hyperplasia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Seborrhoea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
<hr/>						
Skin fissures						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin lesion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Skin mass						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stasis dermatitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urticaria						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
PI	3/ 51 (6%)	1/ 54 (2%)	3.3125 (0.3332, 32.9279) /0.307	4.0305 (-3.3608, 11.4218) /0.285	3.1765 (0.3414, 29.5579) /0.310	0.405
INI	9/102 (9%)	8/ 99 (8%)	1.1008 (0.4069, 2.9781) /0.850	0.7427 (-6.9463, 8.4317) /0.850	1.0919 (0.4389, 2.7163) /0.850	
NNRTI	7/155 (5%)	10/155 (6%)	0.6858 (0.2542, 1.8506) /0.456	-1.9355 (-6.9996, 3.1286) /0.454	0.7000 (0.2735, 1.7918) /0.457	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	3/102 (3%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.138
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	2/155 (1%)	0.4968 (0.0446, 5.5356) /0.569	-0.6452 (-2.8235, 1.5332) /0.562	0.5000 (0.0458, 5.4573) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.241
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bone contusion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epicondylitis PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exposure to communicable disease						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Procedural pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Soft tissue injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Buttock injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection related reaction						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post procedural complication						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Radius fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Road traffic accident						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Skin abrasion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Splinter PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.397
INI	6/102 (6%)	7/ 99 (7%)	0.8214 (0.2661, 2.5360) /0.732	-1.1884 (-7.9962, 5.6195) /0.732	0.8319 (0.2897, 2.3888) /0.732	
NNRTI	13/155 (8%)	6/155 (4%)	2.2735 (0.8412, 6.1446) /0.105	4.5161 (-0.8004, 9.8326) /0.096	2.1667 (0.8452, 5.5542) /0.107	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.076
INI	4/102 (4%)	3/ 99 (3%)	1.3061 (0.2848, 5.9909) /0.731	0.8913 (-4.1676, 5.9501) /0.730	1.2941 (0.2972, 5.6351) /0.731	
NNRTI	6/155 (4%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.306
INI	2/102 (2%)	3/ 99 (3%)	0.6400 (0.1046, 3.9145) /0.629	-1.0695 (-5.3871, 3.2481) /0.627	0.6471 (0.1105, 3.7900) /0.629	
NNRTI	3/155 (2%)	1/155 (<1%)	3.0395 (0.3127, 29.5452) /0.338	1.2903 (-1.2182, 3.7988) /0.313	3.0000 (0.3155, 28.5257) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	2/155 (1%)	0.4968 (0.0446, 5.5356) /0.569	-0.6452 (-2.8235, 1.5332) /0.562	0.5000 (0.0458, 5.4573) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	2/155 (1%)	0.4968 (0.0446, 5.5356) /0.569	-0.6452 (-2.8235, 1.5332) /0.562	0.5000 (0.0458, 5.4573) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute stress disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Affect lability						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Drug abuse						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritability PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Mood altered PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mood swings						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Panic disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thinking abnormal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
PI	0/ 51	3/ 54 (6%)	<0.0001 (<0.0001, -) />0.999	-7.7020 (-36.3576, 20.9537) /0.598	<0.0001 (<0.0001, -) />0.999	0.278
INI	4/102 (4%)	6/ 99 (6%)	0.6327 (0.1730, 2.3135) /0.489	-2.1390 (-8.1624, 3.8844) /0.486	0.6471 (0.1883, 2.2239) /0.490	
NNRTI	5/155 (3%)	9/155 (6%)	0.5407 (0.1770, 1.6518) /0.281	-2.5806 (-7.1949, 2.0337) /0.273	0.5556 (0.1905, 1.6202) /0.282	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
PI	0/ 51	2/ 54 (4%)	<0.0001 (<0.0001, -) />0.999	-5.9276 (-34.4654, 22.6101) /0.684	<0.0001 (<0.0001, -) />0.999	0.358
INI	3/102 (3%)	4/ 99 (4%)	0.7197 (0.1569, 3.3011) /0.672	-1.0992 (-6.1782, 3.9797) /0.671	0.7279 (0.1672, 3.1697) /0.672	
NNRTI	4/155 (3%)	5/155 (3%)	0.7947 (0.2093, 3.0170) /0.736	-0.6452 (-4.3825, 3.0922) /0.735	0.8000 (0.2189, 2.9231) /0.736	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gout						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperglycaemia ^a						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Increased appetite						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decreased appetite						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Impaired fasting glucose						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B12 deficiency						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Investigations						
Any Event						
PI	8/ 51 (16%)	2/ 54 (4%)	4.8372 (0.9754, 23.9896) /0.054	11.9826 (0.8026, 23.1625) /0.036	4.2353 (0.9436, 19.0094) /0.060	0.055
INI	1/102 (<1%)	4/ 99 (4%)	0.2351 (0.0258, 2.1417) /0.199	-3.0600 (-7.3844, 1.2644) /0.165	0.2426 (0.0276, 2.1332) /0.202	
NNRTI	6/155 (4%)	4/155 (3%)	1.5201 (0.4204, 5.4961) /0.523	1.2903 (-2.6407, 5.2214) /0.520	1.5000 (0.4317, 5.2115) /0.523	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood pressure increased						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Alanine aminotransfer ase increased PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,
 OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),
 using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models
 with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical
 estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Body temperature increased						
PI	4/ 51 (8%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine decreased						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Aspartate aminotransfer ase increased						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Activated partial thromboplastin time prolonged						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Blood cholesterol increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Glycosylated haemoglobin increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Hepatic enzyme increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipids increased						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatic enzymes increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thyroxine free decreased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Weight increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye disorders						
Any Event						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.440
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	5/155 (3%)	7/155 (5%)	0.7048 (0.2188, 2.2705) /0.558	-1.2903 (-5.5826, 3.0020) /0.556	0.7143 (0.2317, 2.2020) /0.558	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis allergic						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pruritus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid oedema PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vision blurred						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	
Blepharitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cataract subcapsular PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Conjunctival haemorrhage						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry eye						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Eye pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye swelling						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Ocular hyperaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
PI	0/ 51	2/ 54 (4%)	<0.0001 (<0.0001, -) />0.999	-5.9276 (-34.4654, 22.6101) /0.684	<0.0001 (<0.0001, -) />0.999	0.125
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	6/155 (4%)	5/155 (3%)	1.2081 (0.3609, 4.0442) /0.759	0.6452 (-3.4730, 4.7633) /0.759	1.2000 (0.3740, 3.8500) /0.759	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	3/155 (2%)	0.6623 (0.1091, 4.0197) /0.654	-0.6452 (-3.4488, 2.1585) /0.652	0.6667 (0.1130, 3.9347) /0.654	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deficiency anaemia						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eosinophilia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Leukocytosis						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Microcytic anaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
PI	3/ 51 (6%)	0/ 54	>999 (>999, >999) /NC	8.0142 (-19.9986, 36.0271) /0.575	>999 (>999, >999) /NC	0.086
INI	2/102 (2%)	3/ 99 (3%)	0.6400 (0.1046, 3.9145) /0.629	-1.0695 (-5.3871, 3.2481) /0.627	0.6471 (0.1105, 3.7900) /0.629	
NNRTI	5/155 (3%)	1/155 (<1%)	5.1333 (0.5927, 44.4572) /0.138	2.5806 (-0.4731, 5.6344) /0.098	5.0000 (0.5910, 42.3046) /0.140	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Benign prostatic hyperplasia						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysmenorrhoea PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Menorrhagia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Balanoposthitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cyst						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Breast pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Dysfunctional uterine bleeding						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Menometrorrhagia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menstrual disorder						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Metrorrhagia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Scrotal mass						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal discharge						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal haemorrhage						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Vascular disorders						
Any Event						
PI	4/ 51 (8%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.057
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	5/155 (3%)	3/155 (2%)	1.6889 (0.3966, 7.1929) /0.478	1.2903 (-2.2368, 4.8175) /0.473	1.6667 (0.4053, 6.8535) /0.479	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	3/155 (2%)	1/155 (<1%)	3.0395 (0.3127, 29.5452) /0.338	1.2903 (-1.2182, 3.7988) /0.313	3.0000 (0.3155, 28.5257) /0.339	
Hot flush PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertensive crisis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orthostatic hypotension						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Phlebitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Varicophlebitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicose vein PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Venous thrombosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	0.668
INI	3/102 (3%)	2/ 99 (2%)	1.4697 (0.2403, 8.9892) /0.677	0.9210 (-3.3722, 5.2142) /0.674	1.4559 (0.2486, 8.5276) /0.677	
NNRTI	5/155 (3%)	1/155 (<1%)	5.1333 (0.5927, 44.4572) /0.138	2.5806 (-0.4731, 5.6344) /0.098	5.0000 (0.5910, 42.3046) /0.140	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
PI	0/ 51	0/ 54	NC	NC	NC	>0.999
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Micturition urgency						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Proteinuria						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal impairment						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear and labyrinth disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	4/102 (4%)	2/ 99 (2%)	1.9796 (0.3543, 11.0599) /0.437	1.9014 (-2.7752, 6.5780) /0.426	1.9412 (0.3637, 10.3605) /0.438	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tinnitus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	
Vertigo						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Deafness						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Ear discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Excessive cerumen production						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vertigo positional						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	>0.999
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	3/155 (2%)	3/155 (2%)	1.0000 (0.1987, 5.0330) />0.999	<0.0001 (-3.0672, 3.0672) />0.999	1.0000 (0.2050, 4.8780) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	2/155 (1%)	0.4968 (0.0446, 5.5356) /0.569	-0.6452 (-2.8235, 1.5332) /0.562	0.5000 (0.0458, 5.4573) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Fibrous histiocytoma PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Knuckle pads						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Melanocytic naevus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiac disorders						
Any Event						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.338
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bradycardia PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Cardiovascular disorder PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Palpitations						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Sinus tachycardia						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ventricular extrasystoles						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.535
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Allergy to animal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Mycotic allergy						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypogonadism						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidism						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Thyroid mass						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Social circumstances						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menopause PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress at work						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Hepatobiliary disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Biliary tract disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion missed						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Surgical and medical procedures						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental implantation						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Overall						
Any Event						
PI	20/ 51 (39%)	11/ 54 (20%)	2.5220 (1.0580, 6.0116) /0.037	18.8453 (1.6715, 36.0191) /0.031	1.9251 (1.0270, 3.6087) /0.041	0.892
INI	50/102 (49%)	23/ 99 (23%)	3.1773 (1.7318, 5.8291) /<.001	25.7873 (13.0076, 38.5670) /<.001	2.1100 (1.4015, 3.1766) /<.001	
NNRTI	88/155 (57%)	47/155 (30%)	3.0181 (1.8916, 4.8155) /<.001	26.4516 (15.8128, 37.0904) /<.001	1.8723 (1.4217, 2.4659) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
PI	9/ 51 (18%)	6/ 54 (11%)	1.7143 (0.5633, 5.2169) /0.343	6.5359 (-6.8702, 19.9421) /0.339	1.5882 (0.6084, 4.1459) /0.345	0.761
INI	16/102 (16%)	15/ 99 (15%)	1.0419 (0.4844, 2.2409) /0.916	0.5348 (-9.4499, 10.5194) /0.916	1.0353 (0.5416, 1.9789) /0.916	
NNRTI	33/155 (21%)	29/155 (19%)	1.1752 (0.6730, 2.0524) /0.570	2.5806 (-6.3202, 11.4815) /0.570	1.1379 (0.7282, 1.7783) /0.571	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.417
INI	4/102 (4%)	2/ 99 (2%)	1.9796 (0.3543, 11.0599) /0.437	1.9014 (-2.7752, 6.5780) /0.426	1.9412 (0.3637, 10.3605) /0.438	
NNRTI	6/155 (4%)	1/155 (<1%)	6.2013 (0.7377, 52.1286) /0.093	3.2258 (-0.0622, 6.5138) /0.054	6.0000 (0.7309, 49.2556) /0.095	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Upper respiratory tract infection						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.329
INI	3/102 (3%)	1/ 99 (1%)	2.9697 (0.3037, 29.0436) /0.350	1.9311 (-1.8940, 5.7561) /0.322	2.9118 (0.3081, 27.5217) /0.351	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	4/155 (3%)	0.2451 (0.0271, 2.2184) /0.211	-1.9355 (-4.7318, 0.8608) /0.175	0.2500 (0.0283, 2.2115) /0.213	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.457
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	3/155 (2%)	0.6623 (0.1091, 4.0197) /0.654	-0.6452 (-3.4488, 2.1585) /0.652	0.6667 (0.1130, 3.9347) /0.654	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.123
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	3/155 (2%)	3/155 (2%)	1.0000 (0.1987, 5.0330) />0.999	<0.0001 (-3.0672, 3.0672) />0.999	1.0000 (0.2050, 4.8780) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.144
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	3/155 (2%)	0.3290 (0.0338, 3.1981) /0.338	-1.2903 (-3.7988, 1.2182) /0.313	0.3333 (0.0351, 3.1695) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Lower respiratory tract infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctiviti s						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Gonorrhoea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Sinusitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	3/155 (2%)	0.3290 (0.0338, 3.1981) /0.338	-1.2903 (-3.7988, 1.2182) /0.313	0.3333 (0.0351, 3.1695) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis PI	0/ 51	0/ 54	NC	NC	NC	>0.999
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydial infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.602
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis PI	0/ 51	2/ 54 (4%)	<0.0001 (<0.0001, -) />0.999	-5.9276 (-34.4654, 22.6101) /0.684	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute sinusitis						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Tinea versicolour PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Candida infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Cellulitis						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	>0.999
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.061
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	4/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Onychomycosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Proctitis gonococcal PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Anal chlamydia infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Cystitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site cellulitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis media acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	2/155 (1%)	0.4968 (0.0446, 5.5356) /0.569	-0.6452 (-2.8235, 1.5332) /0.562	0.5000 (0.0458, 5.4573) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Secondary syphilis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	
Staphylococcal infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Subcutaneous abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Tooth abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Cervicitis human papilloma virus PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Folliculitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Groin abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hepatitis A						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
<hr/>						
Infected bite						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Liver abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Localised infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral candidiasis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Periodontitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pertussis PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Proctitis chlamydial PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis herpes						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotavirus infection						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
PI	12/ 51 (24%)	2/ 54 (4%)	8.0000 (1.6921, 37.8220) /0.009	19.8257 (7.1411, 32.5104) /0.002	6.3529 (1.4944, 27.0075) /0.012	NC
INI	39/102 (38%)	1/ 99 (1%)	60.6667 (8.1286, 452.7782) /<.001	37.2252 (27.5908, 46.8595) /<.001	37.8529 (5.3023, 270.2334) /<.001	
NNRTI	55/155 (35%)	2/155 (1%)	42.0745 (10.0366, 176.3812) /<.001	34.1935 (26.4545, 41.9326) /<.001	27.5000 (6.8277, 110.7623) /<.001	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site pain PI	10/ 51 (20%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	36/102 (35%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	45/155 (29%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	6/155 (4%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	>0.999
INI	4/102 (4%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injection site bruising						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site haematoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Oedema peripheral PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral swelling						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Vessel puncture site pain PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
PI	2/ 51 (4%)	2/ 54 (4%)	1.0612 (0.1438, 7.8292) /0.954	0.2179 (-7.1137, 7.5494) /0.954	1.0588 (0.1549, 7.2384) /0.954	0.729
INI	9/102 (9%)	4/ 99 (4%)	2.2984 (0.6840, 7.7230) /0.178	4.7831 (-1.9506, 11.5168) /0.164	2.1838 (0.6950, 6.8616) /0.181	
NNRTI	12/155 (8%)	9/155 (6%)	1.3613 (0.5565, 3.3299) /0.499	1.9355 (-3.6553, 7.5263) /0.497	1.3333 (0.5784, 3.0734) /0.500	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.692
INI	4/102 (4%)	1/ 99 (1%)	4.0000 (0.4392, 36.4309) /0.219	2.9115 (-1.3394, 7.1623) /0.179	3.8824 (0.4416, 34.1318) /0.221	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	3/102 (3%)	3/ 99 (3%)	0.9697 (0.1910, 4.9233) /0.970	-0.0891 (-4.7958, 4.6176) /0.970	0.9706 (0.2007, 4.6944) /0.970	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Toothache						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	
<hr/>						
Dyspepsia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Flatulence						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Gastritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Food poisoning						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Inguinal hernia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	
Odynophagia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Proctitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	3/155 (2%)	0.3290 (0.0338, 3.1981) /0.338	-1.2903 (-3.7988, 1.2182) /0.313	0.3333 (0.0351, 3.1695) /0.339	
<hr/>						
Dental caries						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal hernia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Eosinophilic oesophagitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Functional gastrointestinal disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritable bowel syndrome						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pancreatitis chronic PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis ulcerative						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
PI	3/ 51 (6%)	3/ 54 (6%)	1.0625 (0.2044, 5.5221) /0.943	0.3268 (-8.5629, 9.2165) /0.943	1.0588 (0.2239, 5.0080) /0.943	0.747
INI	7/102 (7%)	6/ 99 (6%)	1.1421 (0.3699, 3.5260) /0.817	0.8021 (-5.9923, 7.5965) /0.817	1.1324 (0.3944, 3.2514) /0.817	
NNRTI	11/155 (7%)	6/155 (4%)	1.8970 (0.6835, 5.2646) /0.219	3.2258 (-1.8301, 8.2817) /0.211	1.8333 (0.6953, 4.8337) /0.220	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.414
INI	4/102 (4%)	1/ 99 (1%)	4.0000 (0.4392, 36.4309) /0.219	2.9115 (-1.3394, 7.1623) /0.179	3.8824 (0.4416, 34.1318) /0.221	
NNRTI	4/155 (3%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
PI	0/ 51	0/ 54	NC	NC	NC	0.927
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
PI	0/ 51	0/ 54	NC	NC	NC	0.822
INI	1/102 (<1%)	3/ 99 (3%)	0.3168 (0.0324, 3.0986) /0.323	-2.0499 (-5.9304, 1.8306) /0.300	0.3235 (0.0342, 3.0580) /0.325	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Muscle contracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Neck pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tendonitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Musculoskeletal chest pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropathy PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Intervertebra l disc disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint effusion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Myositis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteonecrosis PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Polyarthrititis PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal osteoarthritis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
PI	4/ 51 (8%)	1/ 54 (2%)	4.5106 (0.4869, 41.7899) /0.185	5.9913 (-2.2168, 14.1994) /0.153	4.2353 (0.4896, 36.6378) /0.190	0.360
INI	5/102 (5%)	3/ 99 (3%)	1.6495 (0.3835, 7.0948) /0.501	1.8717 (-3.5097, 7.2530) /0.495	1.6176 (0.3972, 6.5887) /0.502	
NNRTI	5/155 (3%)	6/155 (4%)	0.8278 (0.2473, 2.7712) /0.759	-0.6452 (-4.7633, 3.4730) /0.759	0.8333 (0.2597, 2.6736) /0.759	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
PI	2/ 51 (4%)	1/ 54 (2%)	2.1633 (0.1901, 24.6136) /0.534	2.0697 (-4.3575, 8.4970) /0.528	2.1176 (0.1980, 22.6477) /0.535	0.305
INI	3/102 (3%)	1/ 99 (1%)	2.9697 (0.3037, 29.0436) /0.350	1.9311 (-1.8940, 5.7561) /0.322	2.9118 (0.3081, 27.5217) /0.351	
NNRTI	1/155 (<1%)	3/155 (2%)	0.3290 (0.0338, 3.1981) /0.338	-1.2903 (-3.7988, 1.2182) /0.313	0.3333 (0.0351, 3.1695) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Cervicobrachial syndrome						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syncope PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Burning sensation						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebrovascular accident						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysgeusia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Intercostal neuralgia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contractions involuntary						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neuromuscular blockade						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post-traumatic headache						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.476
INI	4/102 (4%)	5/ 99 (5%)	0.7673 (0.1999, 2.9449) /0.700	-1.1289 (-6.8558, 4.5980) /0.699	0.7765 (0.2147, 2.8077) /0.700	
NNRTI	2/155 (1%)	6/155 (4%)	0.3246 (0.0645, 1.6340) /0.172	-2.5806 (-6.0990, 0.9377) /0.151	0.3333 (0.0683, 1.6260) /0.174	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.242
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus congestion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Catarrh						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Productive cough						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract congestion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Lower respiratory tract congestion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchospasm						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Lung disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal septum deviation						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Pneumonitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory distress						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wheezing PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.424
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pruritus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Urticaria						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decubitus ulcer						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intertrigo						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Rash erythematous						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Rash maculo-papular						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
PI	4/ 51 (8%)	1/ 54 (2%)	4.5106 (0.4869, 41.7899) /0.185	5.9913 (-2.2168, 14.1994) /0.153	4.2353 (0.4896, 36.6378) /0.190	0.026
INI	3/102 (3%)	6/ 99 (6%)	0.4697 (0.1142, 1.9326) /0.295	-3.1194 (-8.8503, 2.6114) /0.286	0.4853 (0.1248, 1.8871) /0.297	
NNRTI	11/155 (7%)	2/155 (1%)	5.8437 (1.2733, 26.8186) /0.023	5.8065 (1.3909, 10.2220) /0.010	5.5000 (1.2394, 24.4064) /0.025	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod bite						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	
Epicondylitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exposure to communicable disease						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Procedural pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection related reaction						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radius fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Road traffic accident						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand fracture PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper limb fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Facial bones fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Foot fracture						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Humerus fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injury corneal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint dislocation						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament rupture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Meniscus injury						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Skin injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon rupture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tooth fracture						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
PI	5/ 51 (10%)	0/ 54	>999 (>999, >999) /NC	11.7542 (-16.5766, 40.0850) /0.416	>999 (>999, >999) /NC	0.027
INI	3/102 (3%)	2/ 99 (2%)	1.4697 (0.2403, 8.9892) /0.677	0.9210 (-3.3722, 5.2142) /0.674	1.4559 (0.2486, 8.5276) /0.677	
NNRTI	4/155 (3%)	6/155 (4%)	0.6578 (0.1819, 2.3784) /0.523	-1.2903 (-5.2214, 2.6407) /0.520	0.6667 (0.1919, 2.3162) /0.523	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
INI	0/102	2/ 99 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2950 (-24.5161, 15.9261) /0.677	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Depression suicidal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Drug dependence						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal behaviour						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Suicide attempt						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.603
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	3/155 (2%)	5/155 (3%)	0.5921 (0.1390, 2.5217) /0.478	-1.2903 (-4.8175, 2.2368) /0.473	0.6000 (0.1459, 2.4673) /0.479	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	3/155 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2115 (-20.5981, 12.1752) /0.614	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decreased appetite PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dehydration						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diabetes mellitus						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diabetic ketoacidosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Hypokalaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin B6 deficiency						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Investigations						
Any Event						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.059
INI	4/102 (4%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	4/155 (3%)	6/155 (4%)	0.6578 (0.1819, 2.3784) /0.523	-1.2903 (-5.2214, 2.6407) /0.520	0.6667 (0.1919, 2.3162) /0.523	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Alanine aminotransfer ase increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.564
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Electrocardiogram QT prolonged						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Blood cholesterol increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood glucose increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
ECG signs of ventricular hypertrophy						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Neisseria test positive						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lacrimation increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous haematoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia folate deficiency						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thrombocytopenia						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.531
INI	2/102 (2%)	1/ 99 (1%)	1.9600 (0.1749, 21.9664) /0.585	0.9507 (-2.3839, 4.2853) /0.576	1.9412 (0.1789, 21.0683) /0.586	
NNRTI	2/155 (1%)	2/155 (1%)	1.0000 (0.1391, 7.1903) />0.999	<0.0001 (-2.5126, 2.5126) />0.999	1.0000 (0.1427, 7.0096) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Benign prostatic hyperplasia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menorrhagia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Balanoposthitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adenomyosis PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Breast mass PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital erythema						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	4/155 (3%)	3/155 (2%)	1.3422 (0.2954, 6.0987) /0.703	0.6452 (-2.6616, 3.9519) /0.702	1.3333 (0.3034, 5.8590) /0.703	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypertension						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	4/155 (3%)	2/155 (1%)	2.0265 (0.3657, 11.2291) /0.419	1.2903 (-1.7736, 4.3542) /0.409	2.0000 (0.3717, 10.7603) /0.419	
Deep vein thrombosis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Renal and urinary disorders						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	3/155 (2%)	2/155 (1%)	1.5099 (0.2488, 9.1636) /0.654	0.6452 (-2.1585, 3.4488) /0.652	1.5000 (0.2542, 8.8530) /0.654	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proteinuria						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal impairment						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal colic PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral discharge						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	3/102 (3%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Basal cell carcinoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Skin papilloma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Squamous cell carcinoma of skin						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	>0.999
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Allergy to animal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug hypersensitivity						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypothyroidism						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion spontaneous						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Overall						
Any Event						
PI	4/ 51 (8%)	4/ 54 (7%)	1.0638 (0.2516, 4.4990) /0.933	0.4357 (-9.7247, 10.5962) /0.933	1.0588 (0.2795, 4.0115) /0.933	0.549
INI	8/102 (8%)	3/ 99 (3%)	2.7234 (0.7011, 10.5795) /0.148	4.8128 (-1.4020, 11.0276) /0.129	2.5882 (0.7070, 9.4758) /0.151	
NNRTI	15/155 (10%)	12/155 (8%)	1.2768 (0.5771, 2.8247) /0.546	1.9355 (-4.3387, 8.2096) /0.545	1.2500 (0.6050, 2.5827) /0.547	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.222
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hepatitis A						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Appendicitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis Escherichia coli						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	3/102 (3%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	6/155 (4%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	6/155 (4%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site induration						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal disorders						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.242
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Nausea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Vomiting						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Abdominal pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthralgia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rhabdomyolysis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seizure PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury, poisoning and procedural complications						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Eye injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Anxiety						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
<hr/>						
Depression						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Suicidal ideation						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	2/155 (1%)	0.4968 (0.0446, 5.5356) /0.569	-0.6452 (-2.8235, 1.5332) /0.562	0.5000 (0.0458, 5.4573) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertriglyceridaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Investigations						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.036
INI	4/102 (4%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	4/155 (3%)	0.7451 (0.1640, 3.3855) /0.703	-0.6452 (-3.9519, 2.6616) /0.702	0.7500 (0.1707, 3.2957) /0.703	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Blood creatine phosphokinase increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood phosphorus decreased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Liver function test abnormal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood and lymphatic system disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst ruptured						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic kidney disease						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papillary thyroid cancer						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seminoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class	Q4W IM Preferred Term (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.274
INI	1/102 (<1%)	2/ 99 (2%)	0.4802 (0.0428, 5.3818) /0.552	-1.0398 (-4.4068, 2.3272) /0.545	0.4853 (0.0447, 5.2671) /0.552	
NNRTI	6/155 (4%)	2/155 (1%)	3.0805 (0.6120, 15.5060) /0.172	2.5806 (-0.9377, 6.0990) /0.151	3.0000 (0.6150, 14.6341) /0.174	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	1/ 99 (1%)	0.9703 (0.0599, 15.7297) /0.983	-0.0297 (-2.7749, 2.7155) /0.983	0.9706 (0.0616, 15.3042) /0.983	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	
Acute hepatitis B						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis C						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Pyelonephritis acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	4/155 (3%)	1/155 (<1%)	4.0795 (0.4508, 36.9195) /0.211	1.9355 (-0.8608, 4.7318) /0.175	4.0000 (0.4522, 35.3840) /0.213	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Blood creatinine phosphokinase increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Blood bilirubin increased						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neutropenia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Squamous cell carcinoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hyperbilirubinaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 5

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Overall						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 5

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade,
 System Organ Class, Preferred Term (Maintenance Phase) - by Baseline Third Agent Class - ATLAS

Maximum Toxicity Grade= 5

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	8/ 80 (10%)	2/ 80 (3%)	4.3333 (0.8906, 21.0855) /0.069	7.5000 (0.0891, 14.9109) /0.047	4.0000 (0.8764, 18.2557) /0.074	0.280
35 - <50	22/162 (14%)	15/132 (11%)	1.2257 (0.6082, 2.4700) /0.569	2.2166 (-5.3426, 9.7758) /0.565	1.1951 (0.6463, 2.2099) /0.570	
>=50	5/ 66 (8%)	6/ 96 (6%)	1.2295 (0.3592, 4.2086) /0.742	1.3258 (-6.6867, 9.3382) /0.746	1.2121 (0.3858, 3.8078) /0.742	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	2/ 80 (3%)	0/ 80	>999 (>999, >999) /NC	4.7645 (-18.0370, 27.5659) /0.682	>999 (>999, >999) /NC	0.169
35 - <50	9/162 (6%)	3/132 (2%)	2.5294 (0.6707, 9.5397) /0.171	3.2828 (-1.0652, 7.6309) /0.139	2.4444 (0.6754, 8.8471) /0.173	
>=50	1/ 66 (2%)	3/ 96 (3%)	0.4769 (0.0485, 4.6873) /0.525	-1.6098 (-6.1705, 2.9508) /0.489	0.4848 (0.0515, 4.5606) /0.527	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	4/162 (2%)	1/132 (<1%)	3.3165 (0.3662, 30.0363) /0.286	1.7116 (-1.0989, 4.5220) /0.233	3.2593 (0.3687, 28.8100) /0.288	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood phosphorus decreased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
<35	4/ 80 (5%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35 - <50	7/162 (4%)	0/132	>999 (>999, >999) /NC	6.5203 (-11.1455, 24.1861) /0.469	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain <35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35 - <50	7/162 (4%)	0/132	>999 (>999, >999) /NC	6.5203 (-11.1455, 24.1861) /0.469	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infestations and infestations						
Any Event						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
35 - <50	3/162 (2%)	3/132 (2%)	0.8113 (0.1610, 4.0877) /0.800	-0.4209 (-3.7032, 2.8615) /0.802	0.8148 (0.1672, 3.9706) /0.800	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis C						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Appendicitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis acute						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal disorders						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.167
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Nausea						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis acute						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papillary thyroid cancer						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seminoma						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Squamous cell carcinoma						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertriglyceridaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seizure						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neutropenia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye injury <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhabdomyolysis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbiliru binaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic kidney disease						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Reproductive system and breast disorders						
Any Event						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst ruptured						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	7/ 99 (7%)	6/104 (6%)	1.2428 (0.4027, 3.8354) /0.705	1.3015 (-5.4496, 8.0525) /0.706	1.2256 (0.4267, 3.5203) /0.706	0.658
Male	28/209 (13%)	17/204 (8%)	1.7017 (0.9006, 3.2154) /0.102	5.0638 (-0.9120, 11.0396) /0.097	1.6077 (0.9083, 2.8454) /0.103	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	1/ 99 (1%)	3/104 (3%)	0.3435 (0.0351, 3.3592) /0.358	-1.8745 (-5.6464, 1.8974) /0.330	0.3502 (0.0370, 3.3103) /0.360	0.054
Male	11/209 (5%)	3/204 (1%)	3.7222 (1.0230, 13.5436) /0.046	3.7926 (0.3439, 7.2412) /0.031	3.5789 (1.0132, 12.6418) /0.048	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.513
Male	4/209 (2%)	1/204 (<1%)	3.9610 (0.4389, 35.7437) /0.220	1.4237 (-0.6665, 3.5139) /0.182	3.9043 (0.4401, 34.6355) /0.221	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood phosphorus decreased						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Blood bilirubin increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatinine increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Blood triglycerides						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Liver function test abnormal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Transaminases increased						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	10/209 (5%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Injection site pain						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	9/209 (4%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site induration						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infestations						
Any Event						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.156
Male	4/209 (2%)	3/204 (1%)	1.3073 (0.2889, 5.9151) /0.728	0.4433 (-2.0425, 2.9290) /0.727	1.3014 (0.2949, 5.7427) /0.728	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis A						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Acute hepatitis B						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis C						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Appendicitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Gastroenteritis Escherichia coli						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyelonephritis acute						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Viral infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.738
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Colitis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Abdominal pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diarrhoea						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Nausea						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis acute						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Vomiting						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.031
Male	0/209	3/204 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Papillary thyroid cancer						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seminoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Squamous cell carcinoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	2/204 (<1%)	0.4856 (0.0437, 5.3969) /0.557	-0.5019 (-2.1461, 1.1422) /0.550	0.4880 (0.0446, 5.3406) /0.557	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypertriglyceridaemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hypophosphataemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.053
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Headache						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Seizure						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Anaemia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Neutropenia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Eye injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.091
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Arthralgia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Rhabdomyolysis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Anxiety						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anxiety disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Depression						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatocellular injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbiliru binaemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic kidney disease						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst ruptured						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	25/214 (12%)	11/207 (5%)	2.3569 (1.1282, 4.9239) /0.023	6.3682 (1.0901, 11.6463) /0.018	2.1984 (1.1105, 4.3520) /0.024	0.088
Non-White	10/ 94 (11%)	12/101 (12%)	0.8829 (0.3624, 2.1513) /0.784	-1.2429 (-10.1125, 7.6267) /0.784	0.8954 (0.4060, 1.9745) /0.784	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	10/214 (5%)	4/207 (2%)	2.4877 (0.7677, 8.0613) /0.129	2.7405 (-0.6525, 6.1336) /0.113	2.4182 (0.7706, 7.5891) /0.130	0.481
Non-White	2/ 94 (2%)	2/101 (2%)	1.0761 (0.1485, 7.7970) /0.942	0.1475 (-3.8391, 4.1340) /0.942	1.0745 (0.1544, 7.4749) /0.942	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
White	4/214 (2%)	1/207 (<1%)	3.9238 (0.4349, 35.4025) /0.223	1.3861 (-0.6596, 3.4317) /0.184	3.8692 (0.4361, 34.3292) /0.224	0.507
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood phosphorus decreased						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Blood bilirubin increased						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood cholesterol increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Blood creatinine increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood triglycerides						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Blood triglycerides increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Liver function test abnormal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Transaminases increased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
White	8/214 (4%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	3/ 94 (3%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Injection site pain						
White	7/214 (3%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	3/ 94 (3%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site induration						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infestations and infestations						
Any Event						
White	4/214 (2%)	1/207 (<1%)	3.9238 (0.4349, 35.4025) /0.223	1.3861 (-0.6596, 3.4317) /0.184	3.8692 (0.4361, 34.3292) /0.224	0.376
Non-White	2/ 94 (2%)	2/101 (2%)	1.0761 (0.1485, 7.7970) /0.942	0.1475 (-3.8391, 4.1340) /0.942	1.0745 (0.1544, 7.4749) /0.942	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis A						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Acute hepatitis B						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis C						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Anal abscess						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Appendicitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Gastroenteritis Escherichia coli						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Pyelonephritis acute						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Viral infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.293
Non-White	2/ 94 (2%)	2/101 (2%)	1.0761 (0.1485, 7.7970) /0.942	0.1475 (-3.8391, 4.1340) /0.942	1.0745 (0.1544, 7.4749) /0.942	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	
Abdominal pain						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Nausea						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis acute						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vomiting						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	1/214 (<1%)	3/207 (1%)	0.3192 (0.0329, 3.0942) /0.324	-0.9820 (-2.8489, 0.8850) /0.303	0.3224 (0.0338, 3.0747) /0.325	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Papillary thyroid cancer						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Seminoma						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Squamous cell carcinoma						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.055
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Hypertriglyceridaemia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	
<hr/>						
Hypophosphataemia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Headache						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seizure						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	>0.999
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Neutropenia						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Animal bite						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Eye injury						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skull fracture						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	1/ 94 (1%)	1/101 (<1%)	1.0753 (0.0663, 17.4392) /0.959	0.0737 (-2.7599, 2.9074) /0.959	1.0745 (0.0682, 16.9347) /0.959	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rhabdomyolysis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
White	0/214	2/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Anxiety						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Anxiety disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Depression						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Hepatocellular injury						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbiliru binaemia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic kidney disease						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst ruptured						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overall						
Any Event						
North America	12/ 93 (13%)	10/107 (9%)	1.4370 (0.5904, 3.4978) /0.424	3.5574 (-5.2083, 12.3232) /0.426	1.3806 (0.6254, 3.0478) /0.425	0.076
Europe	19/145 (13%)	7/146 (5%)	2.9943 (1.2180, 7.3611) /0.017	8.3089 (1.8146, 14.8032) /0.012	2.7330 (1.1851, 6.3026) /0.018	
Rest of World	4/ 70 (6%)	6/ 55 (11%)	0.4949 (0.1325, 1.8492) /0.296	-5.1948 (-15.0664, 4.6768) /0.302	0.5238 (0.1554, 1.7651) /0.297	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	4/ 93 (4%)	3/107 (3%)	1.5581 (0.3396, 7.1485) /0.568	1.4973 (-3.6781, 6.6728) /0.571	1.5341 (0.3524, 6.6782) /0.569	0.167
Europe	8/145 (6%)	2/146 (1%)	4.2044 (0.8773, 20.1491) /0.072	4.1474 (-0.0198, 8.3145) /0.051	4.0276 (0.8701, 18.6439) /0.075	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood phosphorus decreased						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
North America	5/ 93 (5%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	5/145 (3%)	0/146	>999 (>999, >999) /NC	5.6819 (-11.2187, 22.5824) /0.510	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
North America	4/ 93 (4%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	5/145 (3%)	0/146	>999 (>999, >999) /NC	5.6819 (-11.2187, 22.5824) /0.510	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	0.222
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis C						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Appendicitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis acute						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.168
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nausea						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis acute						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papillary thyroid cancer						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seminoma						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Squamous cell carcinoma						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertriglyceridaemia						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seizure						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neutropenia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye injury						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhabdomyolysis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
North America	0/ 93	2/107 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1459 (-25.1963, 16.9046) /0.699	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety disorder						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbiliru binaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic kidney disease						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst ruptured						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
PI	5/ 51 (10%)	4/ 54 (7%)	1.3587 (0.3437, 5.3706) /0.662	2.3965 (-8.3458, 13.1388) /0.662	1.3235 (0.3762, 4.6560) /0.662	0.944
INI	9/102 (9%)	5/ 99 (5%)	1.8194 (0.5876, 5.6331) /0.299	3.7730 (-3.2203, 10.7663) /0.290	1.7471 (0.6067, 5.0309) /0.301	
NNRTI	21/155 (14%)	14/155 (9%)	1.5784 (0.7710, 3.2310) /0.212	4.5161 (-2.5118, 11.5441) /0.208	1.5000 (0.7921, 2.8406) /0.213	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.151
INI	4/102 (4%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	7/155 (5%)	5/155 (3%)	1.4189 (0.4404, 4.5712) /0.558	1.2903 (-3.0020, 5.5826) /0.558	1.4000 (0.4541, 4.3159) /0.558	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	3/155 (2%)	1/155 (<1%)	3.0395 (0.3127, 29.5452) /0.338	1.2903 (-1.2182, 3.7988) /0.313	3.0000 (0.3155, 28.5257) /0.339	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood phosphorus decreased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	1/155 (<1%)	1.0000 (0.0620, 16.1318) />0.999	<0.0001 (-1.7825, 1.7825) />0.999	1.0000 (0.0631, 15.8450) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin increased						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	3/102 (3%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	6/155 (4%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
PI	2/ 51 (4%)	0/ 54	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
INI	2/102 (2%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	6/155 (4%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.251
INI	1/102 (<1%)	2/ 99 (2%)	0.4802 (0.0428, 5.3818) /0.552	-1.0398 (-4.4068, 2.3272) /0.545	0.4853 (0.0447, 5.2671) /0.552	
NNRTI	4/155 (3%)	1/155 (<1%)	4.0795 (0.4508, 36.9195) /0.211	1.9355 (-0.8608, 4.7318) /0.175	4.0000 (0.4522, 35.3840) /0.213	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis A						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis C						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Appendicitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	0.242
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Diarrhoea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	
Pancreatitis acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vomiting						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	0.404
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	
Anogenital warts						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Papillary thyroid cancer						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seminoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Squamous cell carcinoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	NC
NNRTI	1/155 (<1%)	2/155 (1%)	0.4968 (0.0446, 5.5356) /0.569	-0.6452 (-2.8235, 1.5332) /0.562	0.5000 (0.0458, 5.4573) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertriglyceridaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypophosphataemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seizure						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood and lymphatic system disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neutropenia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthralgia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhabdomyolysis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	NC
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperbiliru binaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic kidney disease						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Reproductive system and breast disorders						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ovarian cyst ruptured						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overall						
Any Event						
<35	4/ 80 (5%)	2/ 80 (3%)	2.0526 (0.3652, 11.5380) /0.414	2.5000 (-3.3748, 8.3748) /0.404	2.0000 (0.3769, 10.6121) /0.416	0.430
35 - <50	7/162 (4%)	9/132 (7%)	0.6172 (0.2235, 1.7043) /0.352	-2.4972 (-7.8163, 2.8219) /0.357	0.6337 (0.2425, 1.6562) /0.352	
>=50	2/ 66 (3%)	2/ 96 (2%)	1.4687 (0.2017, 10.6968) /0.704	0.9470 (-4.0796, 5.9735) /0.712	1.4545 (0.2101, 10.0688) /0.704	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	3/ 80 (4%)	0/ 80	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.079
35 - <50	3/162 (2%)	3/132 (2%)	0.8113 (0.1610, 4.0877) /0.800	-0.4209 (-3.7032, 2.8615) /0.802	0.8148 (0.1672, 3.9706) /0.800	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
<35	0/ 80	0/ 80	NC	NC	NC	>0.999
35 - <50	1/162 (<1%)	1/132 (<1%)	0.8137 (0.0504, 13.1337) /0.884	-0.1403 (-2.0489, 1.7683) /0.885	0.8148 (0.0515, 12.9031) /0.884	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Appendicitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver abscess						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis acute						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.267
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	1/ 96 (1%)	1.4615 (0.0898, 23.7883) /0.790	0.4735 (-3.1056, 4.0526) /0.795	1.4545 (0.0926, 22.8449) /0.790	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pancreatitis acute						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	2/132 (2%)	0.4037 (0.0362, 4.5021) /0.461	-0.8979 (-3.3056, 1.5099) /0.465	0.4074 (0.0374, 4.4437) /0.461	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papillary thyroid cancer						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seminoma						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis acute						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbiliru binaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	2/132 (2%)	<0.0001 (<0.0001, -) />0.999	-3.7924 (-19.9855, 12.4008) /0.646	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye injury <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion missed						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abortion spontaneous						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest discomfort <35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebrovascular accident						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory distress						
<35	0/ 80	1/ 80 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	5/ 99 (5%)	5/104 (5%)	1.0532 (0.2954, 3.7552) /0.936	0.2428 (-5.7164, 6.2020) /0.936	1.0505 (0.3137, 3.5181) /0.936	0.926
Male	8/209 (4%)	8/204 (4%)	0.9751 (0.3589, 2.6494) /0.961	-0.0938 (-3.8169, 3.6292) /0.961	0.9761 (0.3734, 2.5513) /0.961	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infestations						
Any Event						
Female	2/ 99 (2%)	1/104 (<1%)	2.1237 (0.1895, 23.7976) /0.541	1.0587 (-2.2877, 4.4050) /0.535	2.1010 (0.1936, 22.8065) /0.542	0.735
Male	4/209 (2%)	3/204 (1%)	1.3073 (0.2889, 5.9151) /0.728	0.4433 (-2.0425, 2.9290) /0.727	1.3014 (0.2949, 5.7427) /0.728	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis A						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	
Acute hepatitis B						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Appendicitis						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Liver abscess						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Pneumonia						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Pyelonephritis acute						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	0.971
Male	1/209 (<1%)	1/204 (<1%)	0.9760 (0.0606, 15.7087) /0.986	-0.0117 (-1.3510, 1.3276) /0.986	0.9761 (0.0615, 15.5005) /0.986	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	>0.999
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Pancreatitis acute						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.047
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Papillary thyroid cancer						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seminoma						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Hepatobiliary disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis acute						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatocellular injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbiliru binaemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	2/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Eye injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
Female	1/ 99 (1%)	1/104 (<1%)	1.0510 (0.0648, 17.0361) /0.972	0.0486 (-2.6712, 2.7684) /0.972	1.0505 (0.0666, 16.5665) /0.972	>0.999
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abortion missed						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	
Abortion spontaneous						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebrovascular accident						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Suicidal ideation						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory distress						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	9/214 (4%)	3/207 (1%)	2.9854 (0.7967, 11.1859) /0.105	2.7563 (-0.3873, 5.9000) /0.086	2.9019 (0.7967, 10.5693) /0.106	0.020
Non-White	4/ 94 (4%)	10/101 (10%)	0.4044 (0.1224, 1.3369) /0.138	-5.6457 (-12.7576, 1.4662) /0.120	0.4298 (0.1395, 1.3238) /0.141	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infestations						
Any Event						
White	4/214 (2%)	1/207 (<1%)	3.9238 (0.4349, 35.4025) /0.223	1.3861 (-0.6596, 3.4317) /0.184	3.8692 (0.4361, 34.3292) /0.224	0.213
Non-White	2/ 94 (2%)	3/101 (3%)	0.7101 (0.1160, 4.3466) /0.711	-0.8426 (-5.2553, 3.5700) /0.708	0.7163 (0.1224, 4.1928) /0.711	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Acute hepatitis B						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal abscess						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Appendicitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Liver abscess						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Pyelonephritis acute						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	0/214	0/207	NC	NC	NC	>0.999
Non-White	2/ 94 (2%)	2/101 (2%)	1.0761 (0.1485, 7.7970) /0.942	0.1475 (-3.8391, 4.1340) /0.942	1.0745 (0.1544, 7.4749) /0.942	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	
Pancreatitis acute						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	1/214 (<1%)	2/207 (<1%)	0.4812 (0.0433, 5.3477) /0.552	-0.4989 (-2.1146, 1.1168) /0.545	0.4836 (0.0442, 5.2933) /0.552	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Papillary thyroid cancer						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seminoma						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Hepatobiliary disorders						
Any Event						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis acute						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Hepatocellular injury						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbiliru binaemia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	2/101 (2%)	<0.0001 (<0.0001, -) />0.999	-4.2556 (-25.2401, 16.7290) /0.691	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Animal bite						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Eye injury						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skull fracture						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abortion missed						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Abortion spontaneous						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebrovascular accident						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Suicidal ideation						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory distress						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overall						
Any Event						
North America	4/ 93 (4%)	5/107 (5%)	0.9169 (0.2388, 3.5197) /0.899	-0.3718 (-6.1159, 5.3722) /0.899	0.9204 (0.2546, 3.3273) /0.899	0.117
Europe	8/145 (6%)	4/146 (3%)	2.0730 (0.6102, 7.0425) /0.243	2.7775 (-1.7855, 7.3406) /0.233	2.0138 (0.6200, 6.5407) /0.244	
Rest of World	1/ 70 (1%)	4/ 55 (7%)	0.1848 (0.0200, 1.7030) /0.136	-5.8442 (-13.2489, 1.5605) /0.122	0.1964 (0.0226, 1.7078) /0.140	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
North America	2/ 93 (2%)	1/107 (<1%)	2.3297 (0.2078, 26.1139) /0.493	1.2160 (-2.2504, 4.6824) /0.492	2.3011 (0.2120, 24.9705) /0.493	0.067
Europe	4/145 (3%)	1/146 (<1%)	4.1135 (0.4542, 37.2556) /0.208	2.0737 (-0.9090, 5.0564) /0.173	4.0276 (0.4556, 35.6016) /0.210	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Appendicitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	NC
Rest of World	0/ 70	0/ 55	NC	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Liver abscess						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis acute						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	1/ 93 (1%)	1/107 (<1%)	1.1522 (0.0711, 18.6807) /0.921	0.1407 (-2.6374, 2.9188) /0.921	1.1505 (0.0730, 18.1392) /0.921	0.278
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis acute						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	2/146 (1%)	0.5000 (0.0448, 5.5756) /0.573	-0.6802 (-2.9974, 1.6370) /0.565	0.5034 (0.0462, 5.4913) /0.573	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Papillary thyroid cancer						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seminoma						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis acute						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbiliru binaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	2/ 55 (4%)	<0.0001 (<0.0001, -) />0.999	-5.8629 (-30.5337, 18.8079) /0.641	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye injury						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	1/ 55 (2%)	<0.0001 (<0.0001, -) />0.999	-4.0954 (-28.7415, 20.5508) /0.745	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion missed						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion spontaneous						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebrovascular accident						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory distress						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overall						
Any Event						
PI	4/ 51 (8%)	2/ 54 (4%)	2.2128 (0.3874, 12.6398) /0.372	4.1394 (-4.7945, 13.0733) /0.364	2.1176 (0.4052, 11.0671) /0.374	0.575
INI	3/102 (3%)	4/ 99 (4%)	0.7197 (0.1569, 3.3011) /0.672	-1.0992 (-6.1782, 3.9797) /0.671	0.7279 (0.1672, 3.1697) /0.672	
NNRTI	6/155 (4%)	7/155 (5%)	0.8514 (0.2795, 2.5935) /0.777	-0.6452 (-5.1072, 3.8168) /0.777	0.8571 (0.2948, 2.4925) /0.777	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	0.346
INI	1/102 (<1%)	2/ 99 (2%)	0.4802 (0.0428, 5.3818) /0.552	-1.0398 (-4.4068, 2.3272) /0.545	0.4853 (0.0447, 5.2671) /0.552	
NNRTI	4/155 (3%)	2/155 (1%)	2.0265 (0.3657, 11.2291) /0.419	1.2903 (-1.7736, 4.3542) /0.409	2.0000 (0.3717, 10.7603) /0.419	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis A						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Appendicitis						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver abscess						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyelonephritis acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	2/155 (1%)	1/155 (<1%)	2.0131 (0.1806, 22.4327) /0.569	0.6452 (-1.5332, 2.8235) /0.562	2.0000 (0.1832, 21.8294) /0.570	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Vomiting						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
PI	1/ 51 (2%)	1/ 54 (2%)	1.0600 (0.0645, 17.4071) /0.967	0.1089 (-5.1265, 5.3443) /0.967	1.0588 (0.0680, 16.4845) /0.967	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Papillary thyroid cancer						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seminoma						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatobiliary disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholecystitis acute						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbiliru binaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	2/155 (1%)	<0.0001 (<0.0001, -) />0.999	-3.5634 (-19.9926, 12.8658) /0.671	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skull fracture						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion missed						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abortion spontaneous						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebrovascular accident						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	NC
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths) by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory distress						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	1/ 99 (1%)	<0.0001 (<0.0001, -) />0.999	-3.2693 (-23.6050, 17.0663) /0.753	<0.0001 (<0.0001, -) />0.999	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overall						
Any Event						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	0.501
35 - <50	9/162 (6%)	2/132 (2%)	3.8235 (0.8116, 18.0127) /0.090	4.0404 (-0.0565, 8.1373) /0.053	3.6667 (0.8061, 16.6786) /0.093	
>=50	3/ 66 (5%)	3/ 96 (3%)	1.4762 (0.2887, 7.5490) /0.640	1.4205 (-4.6925, 7.5334) /0.649	1.4545 (0.3028, 6.9867) /0.640	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
<35	1/ 80 (1%)	0/ 80	>999 (>999, >999) /NC	3.5218 (-19.3537, 26.3973) /0.763	>999 (>999, >999) /NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	2/ 66 (3%)	0/ 96	>999 (>999, >999) /NC	5.2786 (-15.9070, 26.4643) /0.625	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Asthenia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site nodule						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infestations						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	3/162 (2%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	
Acute hepatitis B						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	1/ 66 (2%)	0/ 96	>999 (>999, >999) /NC	3.7924 (-17.4287, 25.0134) /0.726	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Memory impairment						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	2/162 (1%)	1/132 (<1%)	1.6375 (0.1468, 18.2599) /0.689	0.4770 (-1.7767, 2.7307) /0.678	1.6296 (0.1494, 17.7748) /0.689	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety disorder						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression <35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression suicidal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	
Diarrhoea						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbiliru binaemia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	1/132 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9887 (-19.3486, 13.3712) /0.720	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	1/162 (<1%)	0/132	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
>=50	0/ 66	0/ 96	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Age (<35 vs. 35 - <50 vs. >=50 years)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal impairment						
<35	0/ 80	0/ 80	NC	NC	NC	NC
35 - <50	0/162	0/132	NC	NC	NC	
>=50	0/ 66	1/ 96 (1%)	<0.0001 (<0.0001, -) />0.999	-3.3031 (-28.1983, 21.5920) /0.795	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	3/ 99 (3%)	3/104 (3%)	1.0521 (0.2073, 5.3403) /0.951	0.1457 (-4.5180, 4.8093) /0.951	1.0505 (0.2171, 5.0821) /0.951	0.158
Male	10/209 (5%)	2/204 (<1%)	5.0754 (1.0982, 23.4566) /0.038	3.8043 (0.6103, 6.9983) /0.020	4.8804 (1.0826, 22.0013) /0.039	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
Female	3/ 99 (3%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Injection site pain						
Female	2/ 99 (2%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Asthenia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site nodule						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site swelling						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infestations and infections						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis A						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Acute hepatitis B						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	3/209 (1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Headache						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	2/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Memory impairment						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	>0.999
Male	2/209 (<1%)	1/204 (<1%)	1.9614 (0.1765, 21.7994) /0.584	0.4667 (-1.1644, 2.0979) /0.575	1.9522 (0.1784, 21.3622) /0.584	
Anxiety						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anxiety disorder						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Depression						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depression suicidal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Suicidal ideation						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Colitis						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	
Diarrhoea						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	0.100
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Hepatocellular injury						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbiliru binaemia						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	1/209 (<1%)	0/204	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
Female	0/ 99	1/104 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2169 (-23.8013, 17.3675) /0.759	<0.0001 (<0.0001, -) />0.999	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
Female	1/ 99 (1%)	0/104	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Male	0/209	0/204	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal impairment						
Female	0/ 99	0/104	NC	NC	NC	NC
Male	0/209	1/204 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	11/214 (5%)	3/207 (1%)	3.6847 (1.0130, 13.4032) /0.048	3.6909 (0.3140, 7.0678) /0.032	3.5467 (1.0038, 12.5315) /0.049	0.313
Non-White	2/ 94 (2%)	2/101 (2%)	1.0761 (0.1485, 7.7970) /0.942	0.1475 (-3.8391, 4.1340) /0.942	1.0745 (0.1544, 7.4749) /0.942	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
White	4/214 (2%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Asthenia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site nodule						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Injection site swelling						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	3/214 (1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis A						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Acute hepatitis B						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	>0.999
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
White	2/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Memory impairment						
White	0/214	0/207	NC	NC	NC	NC
Non-White	1/ 94 (1%)	0/101	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
White	2/214 (<1%)	1/207 (<1%)	1.9434 (0.1749, 21.5967) /0.589	0.4515 (-1.1467, 2.0497) /0.580	1.9346 (0.1768, 21.1730) /0.589	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	
Anxiety						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Anxiety disorder						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Depression						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression suicidal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Suicidal ideation						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	0.102
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	
Diarrhoea						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	1/214 (<1%)	1/207 (<1%)	0.9671 (0.0601, 15.5646) /0.981	-0.0158 (-1.3300, 1.2984) /0.981	0.9673 (0.0609, 15.3629) /0.981	>0.999
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatinine increased						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Liver function test abnormal						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	
Hyperbilirubinaemia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
White	0/214	0/207	NC	NC	NC	NC
Non-White	0/ 94	1/101 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.2478 (-24.3448, 17.8492) /0.763	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
White	1/214 (<1%)	0/207	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal impairment						
White	0/214	1/207 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	NC
Non-White	0/ 94	0/101	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overall						
Any Event						
North America	2/ 93 (2%)	4/107 (4%)	0.5659 (0.1013, 3.1625) /0.517	-1.5878 (-6.2366, 3.0610) /0.503	0.5753 (0.1078, 3.0696) /0.518	0.036
Europe	7/145 (5%)	1/146 (<1%)	7.3551 (0.8933, 60.5581) /0.064	4.1427 (0.4061, 7.8792) /0.030	7.0483 (0.8782, 56.5674) /0.066	
Rest of World	4/ 70 (6%)	0/ 55	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
North America	2/ 93 (2%)	0/107	>999 (>999, >999) /NC	4.4231 (-15.4076, 24.2537) /0.662	>999 (>999, >999) /NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
North America	1/ 93 (1%)	0/107	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infestations						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	3/145 (2%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis A						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	2/145 (1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	2/ 70 (3%)	0/ 55	>999 (>999, >999) /NC	5.1111 (-22.1674, 32.3897) /0.713	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Memory impairment						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety disorder						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression suicidal						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nausea						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	1/ 70 (1%)	0/ 55	>999 (>999, >999) /NC	3.7047 (-23.6135, 31.0229) /0.790	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	>0.999
Europe	1/145 (<1%)	1/146 (<1%)	1.0069 (0.0624, 16.2534) /0.996	0.0047 (-1.8938, 1.9032) /0.996	1.0069 (0.0636, 15.9449) /0.996	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	0/145	1/146 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.9031 (-20.0375, 14.2314) /0.740	<0.0001 (<0.0001, -) />0.999	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperbiliru binaemia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
North America	0/ 93	0/107	NC	NC	NC	NC
Europe	1/145 (<1%)	0/146	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal impairment						
North America	0/ 93	1/107 (<1%)	<0.0001 (<0.0001, -) />0.999	-3.1875 (-24.3551, 17.9801) /0.768	<0.0001 (<0.0001, -) />0.999	NC
Europe	0/145	0/146	NC	NC	NC	
Rest of World	0/ 70	0/ 55	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overall						
Any Event						
PI	2/ 51 (4%)	2/ 54 (4%)	1.0612 (0.1438, 7.8292) /0.954	0.2179 (-7.1137, 7.5494) /0.954	1.0588 (0.1549, 7.2384) /0.954	0.081
INI	6/102 (6%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	5/155 (3%)	3/155 (2%)	1.6889 (0.3966, 7.1929) /0.478	1.2903 (-2.2368, 4.8175) /0.473	1.6667 (0.4053, 6.8535) /0.479	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administrative site conditions						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	3/102 (3%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	3/102 (3%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Injection site nodule						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infestations						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	2/155 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis A						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	>0.999
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Headache						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Memory impairment						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety						
PI	1/ 51 (2%)	0/ 54	>999 (>999, >999) /NC	4.2364 (-23.5877, 32.0605) /0.765	>999 (>999, >999) /NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anxiety disorder						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression suicidal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Suicidal ideation						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Colitis						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	
Diarrhoea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nausea						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Liver function test abnormal						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	1/102 (<1%)	0/ 99	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	NC
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatocellular injury						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperbiliru binaemia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
PI	0/ 51	1/ 54 (2%)	<0.0001 (<0.0001, -) />0.999	-4.1287 (-32.6393, 24.3818) /0.777	<0.0001 (<0.0001, -) />0.999	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	0/155	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	1/155 (<1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	NC
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC selected.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.25

Analysis of Proportion of Subjects with Adverse Events leading to Treatment Discontinuation by SOC and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS

Subgroup: Baseline third agent class (PI vs. INI vs. NNRTI)

System Organ Class Preferred Term	Q4W IM (N=308)	Current ART (N=308)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal impairment						
PI	0/ 51	0/ 54	NC	NC	NC	NC
INI	0/102	0/ 99	NC	NC	NC	
NNRTI	0/155	1/155 (<1%)	<0.0001 (<0.0001, -) />0.999	-2.8548 (-19.4520, 13.7424) /0.736	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported, regardless of SOC's selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.